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Original Research Article

Intramuscular pentazocine versus rectal diclofenac for pain relief after caesarean section: a randomized controlled trial

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ABSTRACT

Background: Caesarean section (CS) commonly causes moderate to severe pain in the first 48 hours after surgery with associated discomfort, delayed ambulation, difficulty initiating breastfeeding and prolonged hospital stay. Adequate analgesia after caesarean section is very important for the patient's comfort, overall wellbeing and recovery. This study compared the analgesic effectiveness of intramuscular Pentazocine with rectal diclofenac following caesarean section and also the side effects of these drugs in Federal Medical Centre, Keffi, North Central Nigeria.

Methods: It was an open label single blinded randomized controlled trial carried out among 240 eligible patients scheduled for either elective or emergency caesarean section. Participants were randomised in the ratio 1:1 to use either rectal diclofenac or intramuscular pentazocine. The effectiveness of the drugs on post caesarean section pain relief and maternal satisfaction were assessed using Visual Analog scale (VAS) and Likert's scale respectively. The side effects of the drugs were also assessed.

Results: Majority of the participants had mild to moderate pain throughout the 24 hours period of the study with most having moderate pain. There was no statistically significance difference in the effectiveness of the drugs among the two groups ($p=0.745$), however maternal satisfaction was higher with the rectal diclofenac group compared with the intramuscular pentazocine group ($p=0.017$).

Conclusions: This study showed that suppository diclofenac and intramuscular pentazocine are comparable in pain relief post caesarean section but there was better maternal satisfaction with suppository diclofenac use compared to intramuscular pentazocine use.

Keywords: Analgesia, Caesarean section, Maternal satisfaction, Pain, Side effects

INTRODUCTION

Caesarean section (CS) is a very common obstetric surgery performed worldwide which has saved the lives of many mothers and infants.¹ CS commonly induces moderate to severe pain in the immediate 48 hours post-op.^{1,2} Pain is an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.² Postoperative pain is one of the main postoperative adverse outcomes causing distress to patients. Pain perception is multifactorial; it begins with tissue damage which triggers chains of neuronal activities. Post CS pain consists of two different

pain sensations, the somatic pain from the wound and the visceral pain from the uterine contractions. The somatic pain is well localized and wanes within 1–2 days while the visceral pain is a more diffuse pain taking longer days to wane off.³

Postoperative pain leads to patient's discomfort and suffering, decreased level of satisfaction, prolonged recovery and hospital stay, higher health care costs and increased risk of developing chronic persistent pain.⁴ Postoperative pain is worst in obstetric patients where it interferes with ambulation, breastfeeding and early maternal bonding with the infant. Postoperative pain might lead to thrombo-embolic events due to its limitation of

patient mobility, uterine sub involution and postpartum haemorrhage as well as stress on the health care system.⁵

Effective pain relief promotes early mobilization and good mother-child interactions.^{5,6} Established methods of postoperative pain relief include infiltration of surgical wound with local anaesthetic agent, continuous epidural, oral, intramuscular, intravenous and rectal analgesia.⁶

Intramuscular pentazocine, a partial agonist opioid is widely used in low resource countries for postoperative analgesia but has its limitations.⁷ Non-steroidal anti-inflammatory drugs (NSAIDs) have beneficial effect on postoperative analgesia and are devoid of adverse effects associated with opioids such as sedation, respiratory depression, nausea and vomiting. NSAIDs also reduce pain of uterine contraction by inhibiting prostaglandin synthesis. Diclofenac sodium, a NSAID, is readily available as an oral, intramuscular or rectal medication. Intramuscular diclofenac is painful and oral absorption unpredictable in the perioperative period.^{2,9} The rectal route offers rapid absorption of low molecular weight drugs, partial avoidance of first pass metabolism leading to improvement in rate-controlled drug delivery and absorption.^{8,9} Although awareness and use of rectal diclofenac among Nigerian physician anaesthetists is limited, its role in post caesarean section pain relief is recognized elsewhere.⁹

To reduce postoperative pain, different drugs including opioids and non-steroidal anti-inflammatory drugs (NSAIDs) have been used. This study compared the analgesic effectiveness of intramuscular Pentazocine with rectal diclofenac in the reduction of pain following caesarean section in Federal Medical Centre, Keffi North Central Nigeria.

METHODS

This was a single blind randomized controlled study carried out between April 2023 and September 2023. The sample size was determined using the formula for comparing two sample groups when the outcome variable is quantitative (pain score) using a previous study, the μ_1 =mean NRS in the rectal group=24.5, μ_2 =mean NRS in the intramuscular group=21.6.^{10,11} With attrition rate of 10%, the calculated sample size was 120 participants in each group, making a total of 240 participants. It was carried out in the Obstetrics ward of the Federal Medical Centre Keffi, North central Nigeria.

Inclusion criteria

The inclusion criterion was patients going in for either elective or emergency caesarean delivery under spinal anaesthesia that gave their consent.

Exclusion criteria

The exclusion criteria includes caesarean delivery under general anaesthesia, epidural combined spinal, patients

with medical conditions known to potentially exacerbate non-steroidal anti-inflammatory drugs such as peptic ulcer disease, renal disease, Asthma liver disease, history of allergy to either of the study medications, patients with bleeding disorders, any patient who requires special post-operative pain control such as sickle cell disease and patients who did not consent to the study. Consent for study participation was taken from the participant and an envelope with a study number was given to her to collect her analgesic pack from the theatre pharmacy. Detailed history and thorough physical examination were conducted and a structured proforma appropriately filled. Spinal anaesthesia using 3 ml of 0.5% (15 mg) Bupivacaine hydrochloride was used for all Caesarean sections carried out by competent Obstetrics specialists.

The rectal diclofenac group had a dose of 100 mg 12 hourly for 48 hours, starting immediately after vulvo-vaginal toileting, on the operating table and then 12 hourly for 48 hours in the postnatal ward. Those in the intramuscular pentazocine group had a dose of 60 mg 6 hourly for 48 hours administered immediately after vulvo-vaginal toileting, on the operating table and then 6 hourly for 48 hours in the postnatal ward. These drugs were administered by nurses who were trained about the study. Intravenous paracetamol was used as rescue analgesia at a dose of 600 mg, given if patients complained of significant pain or when the pain score on the visual analogue scale was severe. The time of administration of rescue analgesia was noted as well as the number of doses of rescue analgesia administered to the subjects in the different study groups within the period of 48 hours.

Voltaren® manufactured by Delpharm Huningue S.A.S., Huningue, France for Novartis Pharma AG, Basel, Switzerland, a reputable pharmaceutical company was the brand of rectal diclofenac sodium used. Pilat® manufactured by Belco Pharma, Bahadurgarh Haryana, India and marketed by May and Baker Nigeria PLC, Ikeja, Lagos was the brand of parenteral pentazocine used. Both had manufactory date, expiry date, batch number and NAFDAC registration number. Post-operative pain was evaluated using the visual analogue scale while the maternal satisfaction was assessed using 5-point Likert's scale. The possible side effects of the analgesic drugs were recorded.

Data generated was entered and analysed using the IBM Statistical Package for Social Sciences Software, version 26.0 (Microsoft Chicago IL, United States). The data was presented in tables and graphs with VAS presented as median and range and expressed as frequencies and percentages. Independent Samples Median test and the Pearson's Chi-square or Fisher's exact test were used to compare the level of pain and the maternal satisfaction between the two groups respectively. Significant associations were subjected to Logistic Regression while a p value<0.05 was considered statistically significant.

Trial registration

Before the trial commenced, it was registered (on 13 February 2024) with the Pan African Clinical Trial Registry with reference number PACTR 202402735520583. Reporting was done according to the CONSORT checklist.

Ethical clearance was obtained from the ethical review board of the Federal Medical Centre, Keffi.

RESULTS

A total of two hundred and forty (240) booked pregnant women scheduled for either elective or emergency caesarean section under spinal anaesthesia, were recruited from 3rd April 2023 to 30th of September 2023. Majority of the participants were within the ages of 30–34 years with 37.2% of them in the rectal diclofenac group and 35.6% in the intramuscular pentazocine group. There was no significant difference in the socio-demographic characteristics between participants in both groups. The obstetrics characteristics of both groups are similar with no statistical significance between them. The duration of surgery was similar in both groups with no statistical difference. The level of pain at 6 hours, 12 hours, 18 hours and 24 hours were similar in both groups and not statistically significant. ($p=0.745, 0.259, 0.084$ and 0.122 respectively). 61.2% in the rectal diclofenac group and 66.9% in the intramuscular pentazocine group had rescue analgesia. This was not statistically significant $p=0.348$. Maximum and minimum number of hours to request for rescue analgesia in the rectal diclofenac group was 0 and 15.50 hours respectively while it was 1 hour and 40 hours in the intramuscular pentazocine group. This was not statistically significant.

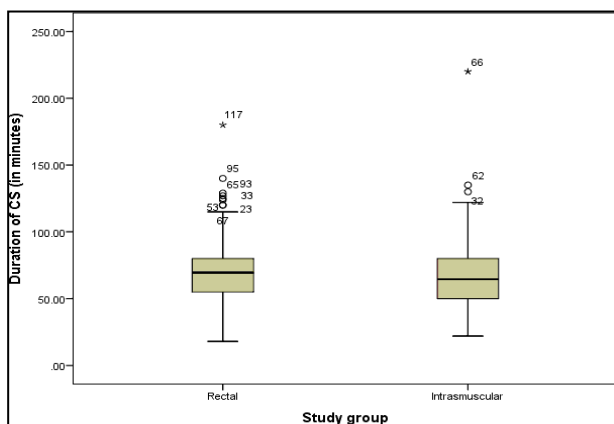


Figure 1: Duration of caesarean section in (in minutes).

Standardized U-test=1.184, p value=0.236.

Both groups had an average of one rescue analgesia used throughout the study period, $p=0.574$. The level of side effects in both groups was similar with 5% of participants in both groups affected. This was also not statistically significant. The main adverse effect in the rectal diclofenac

group was local while the pentazocine experienced systemic symptoms. The level of maternal satisfaction was higher in the rectal diclofenac group than the intramuscular pentazocine group. This was statistically significant ($p=0.017$).

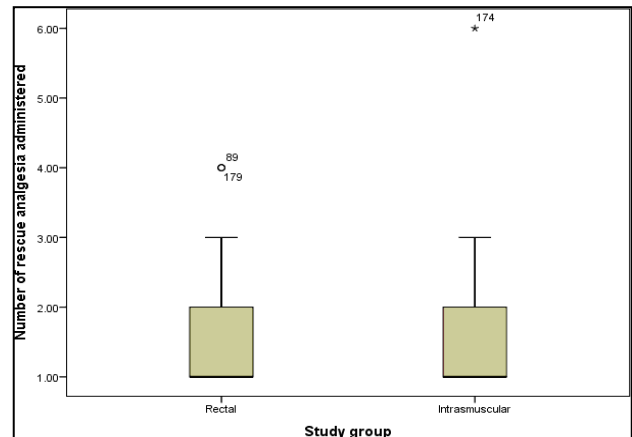


Figure 2: The number of participants in each group that had rescue analgesia.

$\chi^2=0.879$, $p=0.348$

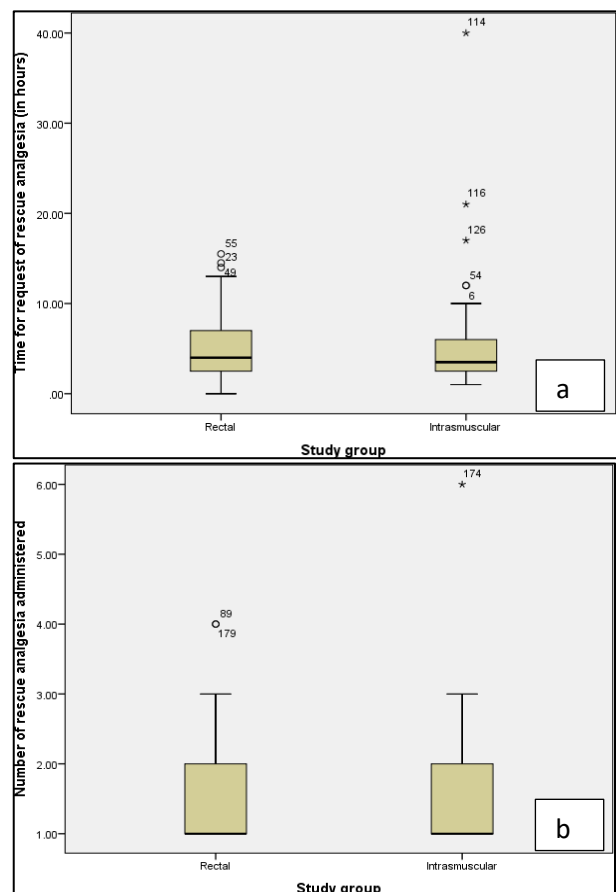


Figure 3: (a) Comparison of time of request for rescue analgesia. (b) Number of times rescue analgesia was administered among the study participants.

Standardized U-test=0.479; p -value=0.632, Standardized U-test=0.563.

Table 1: Socio-demographic characteristics of the study participants.

Study group	Rectal Diclofenac (120), N (%)	Intramuscular Pentazocine (120) N (%)	Total N (%)	χ^2	df	P value
Age (in years)				3.277	5	0.657
<20	0 (0.0)	1 (0.8)	1 (0.4)			
20-24	8 (6.7)	7 (5.8)	15 (6.3)			
25-29	38 (31.7)	33 (27.5)	71 (29.6)			
30-34	45 (37.5)	43 (35.8)	88 (36.6)			
35-39	22 (18.3)	23 (19.2)	45 (18.8)			
40-44	7 (5.8)	13 (10.8)	20 (8.3)			
Mean (SD)						
Religion				4.522	1	0.033
Christianity	77 (64.2)	93 (77.5)	170 (70.8)			
Islam	43 (35.8)	27 (22.5)	70 (29.2)			
Ethnicity				5.334	3	0.149
Hausa	27 (22.5)	16 (13.3)	43 (17.9)			
Igbo	9 (7.5)	17 (14.2)	26 (10.8)			
Yoruba	9 (7.5)	9 (7.5)	18 (7.5)			
Others	75 (62.5)	78 (65.0)	153 (63.8)			
Education				4.709	3	0.194
Non formal	4 (3.3)	3 (2.5)	7 (2.9)			
Primary	12 (10.0)	4 (3.3)	16 (6.7)			
Secondary	38 (31.7)	38 (31.7)	76 (31.7)			
Tertiary	66 (55.0)	75 (62.5)	141 (58.7)			
Occupation				3.018	6	0.807
Civil servant	24 (20.0)	31 (25.8)	55 (22.9)			
Trading	27 (22.5)	28 (23.4)	55 (22.9)			
Farming	3 (2.5)	3 (2.5)	6 (2.5)			
Artisan	9 (7.5)	7 (5.8)	16 (6.7)			
Housewife	50 (41.7)	48 (40.0)	98 (40.8)			
Unemployed	1 (0.8)	0 (0.0)	1 (0.4)			
Student	6 (5.0)	3 (2.5)	9 (3.8)			
Marital status				1143	2	0.565
Single	3 (2.5)	4 (3.3)	7 (2.9)			
Married	116 (96.7)	116 (96.7)	232 (96.7)			
Divorced	1 (0.8)	0 (0.0)	1 (0.4)			

Fisher's exact test interpreted for expected count of <5 while chi-square with Yate's continuity was interpreted for df of 1.

Table 2: Maternal obstetric characteristics.

Obstetrics characteristics	Rectal Diclofenac N (%)	Intramuscular Pentazocine N (%)	Total N (%)	χ^2	df	P value
Parity				7.831	3	0.050
0	16 (13.3)	31 (25.8)	47 (19.6)			
1	31 (25.8)	35 (29.2)	66 (27.5)			
2-4	63 (52.5)	47 (39.2)	110 (45.8)			
5 and above	10 (8.4)	7 (5.8)	17 (7.1)			
Median; Min, Max	2.00; 0.0, 8.0	1.00; 0.0, 8.0	2.00; 0.0, 8.0			
living children				5.528	3	0.137
0	29 (24.2)	41 (34.2)	70 (29.2)			
1	31 (25.8)	30 (25.0)	61 (25.4)			
2-4	55 (45.8)	40 (33.3)	95 (39.6)			
5 and above	5 (4.2)	9 (7.5)	14 (5.8)			

Continued.

Obstetrics characteristics	Rectal Diclofenac N (%)	Intramuscular Pentazocine N (%)	Total N (%)	χ^2	df	P value
Gestational age				1.334	3	0.721
Pre-term	25 (20.8)	21 (17.5)	46 (19.2)			
Early term	64 (53.3)	62 (51.7)	126 (52.5)			
Full term	24 (20.0)	26 (21.7)	50 (20.8)			
Post date	7 (5.9)	11 (9.1)	18 (7.5)			
Mean (SD)	37.77 (2.42)	37.98 (1.99)	37.87 (2.21)			

Significant at $p < 0.05$ **Table 3: Comparison of the level of pain experienced among the study participants.**

Study group	Rectal Diclofenac N (%)	Intramuscular Pentazocine N (%)	Total	χ^2	P value
Level of pain					
6 hours post-CS				0.59	0.745
Mild	13 (10.8)	8 (6.7)	21 (8.8)		
Moderate	94 (78.3)	97 (80.8)	191 (79.6)		
Severe VAS score	13 (10.8)	15 (12.5)	28 (11.6)		
(Median; Min, Max)	5.0; 0.0, 8.0	5.0; 0.0, 8.0	5.0; 0.0, 8.0		
12 hours post-CS				2.702	0.259
Mild	20 (16.7)	12 (10.0)	32 (13.3)		
Moderate	90 (75.0)	94 (78.3)	184 (76.7)		
Severe	10 (8.3)	14 (11.7)	24 (10.0)		
VAS score (Median; Min, Max)	4.0; 0.0, 8.0	5.0; 0.0, 7.0	5.0; 0.0, 8.0		
18 hours post-CS				4.959	0.084
Mild	36 (30.0)	24 (20.0)	60 (25.0)		
Moderate	81 (67.5)	88 (73.3)	169 (70.4)		
Severe	3 (2.5)	8 (6.7)	11 (4.6)		
VAS score (Median; Min, Max)	4.0; 0.0, 7.0	4.0; 0.0, 10.0	4.0; 0.0, 10.0		
24 hours post-CS				4.03	0.122
Mild	55 (45.8)	40 (33.3)	95 (39.5)		
Moderate	63 (52.5)	78 (65.0)	141 (58.8)		
Severe	2 (1.7)	2 (1.7)	4 (1.7)		
VAS score (Median; Min, Max)	4.0; 0.0, 7.0	4.0; 0.0, 8.0	4.0; 0.0, 8.0		

 χ^2 represents chi-square, Note: Fisher's exact interpreted for expected count of < 5 .**Table 4: Comparison of level of side effects experienced by the study participants.**

Study group	Rectal Diclofenac N (%)	Intramuscular Pentazocine N (%)	Total	Statistic	P value
Experience side effect				0.000	1.000
Yes	6 (5.0)	6 (5.0)	12 (5.0)		
No	115 (95.0)	115 (95.0)	230 (95.0)		

 χ^2 represents chi-square with continuity correction.**Table 5: Comparison of adverse effects experienced by the study participants.**

Study group	Rectal Diclofenac N (%) (6)	Intramuscular Pentazocine N (%) (6)	Total N (%) (12)	χ^2	P value
Type of adverse effect				2.000	0.368
Nausea/vomiting	0 (0.0)	1 (16.7)	1 (8.3)		
Drowsiness	0 (0.0)	1 (16.7)	1 (8.3)		
Local irritation	1 (16.7)	0 (0.0)	1 (8.3)		

Fisher's exact interpreted

Table 6: Maternal satisfaction.

Study group	Rectal Diclofenac N (%)	Intramuscular Pentazocine N (%)	Total N (%)	χ^2_t	P value
Maternal satisfaction					
24 hours post-cs					
Very satisfied					
Satisfied	117 (96.7)	106 (87.6)	223 (92.1)	5.712	0.017
Neutral					
Unsatisfied	4 (3.3)	15 (12.4)	19 (7.9)		
Very unsatisfied					

χ^2_t represents chi-square with Yate's continuity correction, Significant at $p < 0.05$

DISCUSSION

Pain is one of the commonest complaints following caesarean section. Pain management is a key aspect of post-operative care which is vital for early ambulation and overall patient's recovery.² Pain free state after caesarean section is necessary for caesarean section patients to cope with the care for their babies, regular breast feeding to enhance maternal and infant bonding.^{5,6} Negative clinical consequences of poor pain relief following caesarean section may lead to prolonged hospital stay, increase financial burden and increase maternal morbidity.⁴ Also there is no gold standard yet for pain relief after caesarean section.⁵ This current study confirmed rectal diclofenac as an effective analgesia for pain relief after caesarean section as majority of the participants had mild to moderate pain throughout the study period.

The VAS was similar in both groups but with better scores in the rectal diclofenac group. At 6 hours post operation both groups had an average VAS of 5 and a maximum of 8 respectively. An average VAS of 4 and 5 was noted in the rectal diclofenac group and intramuscular pentazocine group respectively at 12 hours post operation while a maximum score of 7 and 8 respectively was noted in same group at same hour. At 12th and 24th hours, both group had the same average VAS of 4 but differ in their maximum score (7 at 12th and 24th hour for the rectal group and scores of 10 and 8 for the intramuscular group at 12th and 24th hour assessment respectively).

The VAS though less in the rectal diclofenac group throughout the study period was not statistically significant. This was similar to the findings of Uzoma et al, which concluded that rectal route of diclofenac administration had an advantage over the intramuscular route.¹² Zulfiquar et al, in their study also noted that mean VAS was less in the rectal diclofenac group compared to the intramuscular group.¹³ This similar findings with Uzoma et al, and Zulfiquar et al, could be as a result of similar dose of study drugs and similar dosing interval used in their study. Onuora et al, noted no significant difference in VAS between those that received rectal diclofenac and those that received intramuscular diclofenac in their study and concluded that diclofenac administered through the rectal route is as efficacious as

diclofenac administered via the intramuscular route for post caesarean section analgesia after spinal anaesthesia.¹⁴

This was also similar to the findings of this study in which there were no significant difference in the VAS of the 2 groups and could be as a result of similar demographic profiles of the participants.

This was however different from the findings of Rashid et al, who in their study noted the mean level of post-operative pain after 24 hours using VAS was significantly less in the diclofenac suppository group than in the group which did not receive (1.8 versus 3.7).¹⁶ This could be due to the smaller sample size of 40 participants in each arm of their study compared to 120 participants use in each group of this study.

These findings are also similar to those of Iribhogbe and Sapkai et al, who found suppository diclofenac to be more effective than intramuscular morphine and rectal glycerine respectively.^{16,17} Rita et al, also in comparing suppository diclofenac to injectable tramadol found diclofenac suppository to have better analgesic effect when compared to injectable tramadol with significantly lower pain scores in the suppository diclofenac group compared to the tramadol and placebo groups.¹⁸ This study also reported lower pain scores with the suppository diclofenac group compared to the intramuscular pentazocine group although not statistically significant. This is due to the larger sample size of 240 used in this study compared to a sample size of 150 used by Rita et al, and was further divided into 3 groups.¹⁸

The time between the commencement of the study drugs postoperatively and the time for demand of rescue analgesia in each group in this study and the number of rescue analgesia used in each group were comparable but not statistically significant ($p=0.632$ and 0.574). Even though they were comparable, time for demand of rescue analgesia was longer in the rectal diclofenac group (minimum of 4 hours) compared to the intramuscular pentazocine group (minimum of 3 hours 50 minutes).

The number of rescue analgesia used was also lower in the rectal diclofenac group (maximum of 4) compared to the intramuscular pentazocine group (maximum of 6). This was similar to the findings of Uzoma et al, Zulfiquar et al,

and Khan et al, in their respective studies.^{12,13,19} This could be as a result of same dose and similar dosing interval in their study and the current study. The findings of fewer need for rescue analgesia observed with the suppository diclofenac may be due to effective absorption from the rectal route as well as the prolonged analgesic effect offered by the rectal route compared to the intramuscular route.

No significant side effects were noted in both groups in this study. This could be because the doses of the drugs were at recommended therapeutic doses. Five percent of the participants in each group reported side effect of the study drugs while 95% in each of the groups did not show any side effects. This indicates that suppository diclofenac sodium and intramuscular pentazocine administered for pain relief after caesarean section are tolerable.

There was no observed side effect in the rectal diclofenac group from the study by Uzoma et al, while 5 participants in the intramuscular group had side effects such as nausea, vomiting headache and dizziness.¹² This could be as a result of smaller sample size of 33 used in each group in their study compared to 120 participants used in each group in our study. This was equally different from the studies of Onuora et al, Zulfaqr et al, Khan et al and Altaf et al which in their separate studies did not note any side effects/adverse effects.^{13,14,19,20} This could be that it was not part of their outcome measures or smaller sample size in some of the studies.

This study found a significant difference in maternal satisfaction between the 2 groups at the 24 hours post operation. Maternal satisfaction was better in the rectal diclofenac group at this time compared to the intramuscular pentazocine group and this was statistically significant ($p=0.017$). This was different from the study by Uzoma et al, that noted over all maternal satisfaction to be similar in the rectal and intramuscular group and the study by Onuora et al, that did not find any difference in maternal satisfaction. Significant satisfaction with the suppository diclofenac may be due to the non-invasive nature unlike the use of injections that may be painful.

Rectal diclofenac from this study have shown to provide effective analgesia when given after caesarean section with a tolerable side/adverse effect profile. This will promote injection safety and help to reduce morbidity resulting from pain following caesarean section. The strength of this study is based on the large sample size of 240 participant compared to other similar studies with smaller sample size.

This study had limitations which included the variation in the way individuals respond to pain, the subjective nature of visual analogue scale used for pain assessment, the difference in tissue handling by different surgeons as extensive tissue handling may lead to more post-operative pain that may affect the VAS and the difference in surgical speed by different surgeons, as the longer the procedure the more likely the wearing off of the spinal anaesthesia

which may necessitate the anaesthetist to add other analgesic agents that may affect the VAS.

CONCLUSION

This study showed that suppository diclofenac and intramuscular pentazocine are comparable in pain relief and need for rescue analgesia but show better patient's satisfaction with suppository diclofenac when used for post caesarean section pain relief.

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Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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