Research Article

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Rectal Diclofenac *Versus* Intramuscular Pentazocine for Pain Relief After Caesarean Section: Maternal Satisfaction: A Randomized Controlled Trial

Jesse T Atongo[1], Onazi Ochima [1], Oyiga Favour Ochima[2], Samuel Chimezie Ezekwere[3]

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Abstact:

Background: Caesarean section is one of the most common operative procedures in contemporary Obstetrics practice. Effective post-operative pain management significantly affects maternal acceptability of the procedure and reduces surgical morbidity.

Aim: The study is to compare maternal satisfaction on the use of rectal diclofenac suppository with intra-muscular pentazocine for pain management following caesarean section at Federal Medical Centre Keffi.

Materials and Method: This is an open label single blind randomized controlled trial of diclofenac suppository versus intramuscular pentazocine involving 240 consenting eligible patients scheduled for caesarean delivery at FMC Keffi. Participants were randomized in ratio 1:1, using computer software randomizer. Group 'A' received rectal diclofenac 100 mg 12hrly for 48hrs post-op while group 'B' received intramuscular pentazocine 60 mg 6hrly for 48hrs post-op.

Pain intensity was assessed using the Visual Analog scale (VAS) and Likert's scale was used to assess maternal satisfaction at 24 hours post caesarean section.

Results: The intensity of pain was similar between the two arms, with most participants having moderate pain. There was no statistically significance difference between the two groups (p = 0.745). Mothers in the rectal suppository group expressed more satisfaction compared to those who received intramuscular pentazocine and this was statistically significant, p = 0.017 (p <0.05).

Conclusion: Diclofenac suppository shows better patient satisfaction when used for post-caesarean section pain relief compared to intramuscular pentazocine, though both are comparable in pain relief.

Keywords: Analgesia; Caesarean section; intramuscular pentazocine; maternal satisfaction; rectal diclofenac

[1]Infertility and Reproductive Unit, Obstetrics and Gynaecology Department, Federal Medical Centre, Keffi, Nasarawa State, Nigeria.

[2]Department of Public Health, David Umahi Federal University of Health Sciences, Uburu, Ebonyi State, Nigeria. e-mail ochimaoyiga2007@gmail.com

[3]Eagle Mountain Specialist Hospital, Abuja, Nigeria.

***Corresponding Author:** Onazi Ochima, Infertility and Reproductive unit, Obstetrics and Gynaecology Department, Federal Medical Centre Keffi Nasarawa state, Nigeria.

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Introduction

With improvement in surgical techniques and safety, caesarean section has become widely available, with incidence increasing worldwide.[1]

Pain following the procedure is one of the most common morbidities associated with the procedure. Significant post-operative pain impacts early ambulation, breastfeeding, early mother-child bonding and maternal acceptability of the procedure.[2]

Post-operative pain management has evolved with time in an attempt to make it a positive maternal birth experience. In line with global best practice, maternal care should be patient-centered, including the use of an ideal analgesia in pain management. Various modalities of pain relief have been used over time this includes infiltration of the site of surgical incisions with local anaesthetic agents, continuous epidural, intramuscular injections, intravenous route and rectal suppository analgesia.[3]

An ideal analgesia should not only be effective in relieving pain and free from side effects but should also be well tolerated and accepted. Maternal satisfaction in post-operative pain relief will enhance early ambulation, thus promoting wound healing, reducing the incidence of thrombo-embolic events in susceptible individuals. It will also promote early mother and infant bonding, lower the cost of treatment and improve overall wellbeing.

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To reduce post-operative pain, different drugs, including opioids and non-steroidal anti-inflammatory drugs (NSAIDs), have been used with varying effectiveness and patient satisfaction. This study is therefore aimed at comparing maternal satisfaction in post-operative pain relief with the use of intramuscular pentazocine versus rectal Diclozc following caesarean section in Federal Medical Centre, Keffi.

Materials and Methods

Study Design

This was a single blind randomized controlled study

Study Location

The study was carried out in the Obstetrics unit Federal Medical Centre, Keffi, Nasarawa State.

Study Population

All consenting pregnant women scheduled for caesarean section at the Federal Medical Centre, Keffi, were recruited into the study.

Study Duration

The study lasted from April to September 2024 at the Department of Obstetrics and Gynaecology of the Federal Medical Centre, Keffi, Nigeria.

Only patients scheduled for caesarean delivery under spinal anaesthesia who gave their consent were included in the study.

Exclusion criteria include patients who had caesarean delivery under other forms of anaesthesia, medical conditions where the use of either drug is contradicted, such as chronic liver disease, renal disease, bleeding peptic ulcer disease and Asthma, history of allergy to either of the study medications, bleeding disorders and non-consenting patients.

Sample Size Determination

Using the formula for comparing two sample groups when the outcome variable is quantitative (pain score).[4] with μ_1 = mean NRS in the rectal group= 24.5, μ_2 = mean NRS in the intramuscular group = 21.6, from a previous study [5] and attrition rate of 10% the calculated sample size was 120 participants in each arm, making a total of240 participants.

Study Procedure

Following the recruitment of eligible consenting pregnant women scheduled for caesarean delivery, each patient on admission was asked to pick a sealed envelope containing a study number used to collect the corresponding analgesic drug. The first dose was given in theatre, while subsequent doses were given in the postnatal wards.

A detailed clinical evaluation was conducted and a structured proforma was appropriately filled. All participants recruited for the study had a caesarean section under spinal anaesthesia using the same local anaesthetic agent, 3mls of 0.5% (15 mg) bupivacaine hydrochloride.

Surgeons of a similar cadre carried out the caesarean sections. The dosage for the rectal diclofenac was 100 mg 12-hourly for a duration of 48 hours. The first dose was administered immediately after vulvo-vaginal toileting while the patient was still on the operating table and then every 12 hourly for 48 hours in the postnatal ward.

The dosage for the intramuscular pentazocine was 60 mg 6-hourly for a duration of 48 hours. The first dose of 60 mg intramuscular pentazocine was administered immediately after vulvo-vaginal toileting while the patient was still on the operating table and then 6 hourly for 48 hours in the postnatal ward. The intramuscular analgesic was administered by nurses who were trained about the study.

Whenever the pain score on the visual analogue scale reached a moderate to severe level or when the patient complained of severe pain, 600 mg of Intravenous paracetamol was given as rescue analgesia. The time and number of rescue analgesics given were noted in the two groups within the study periods.

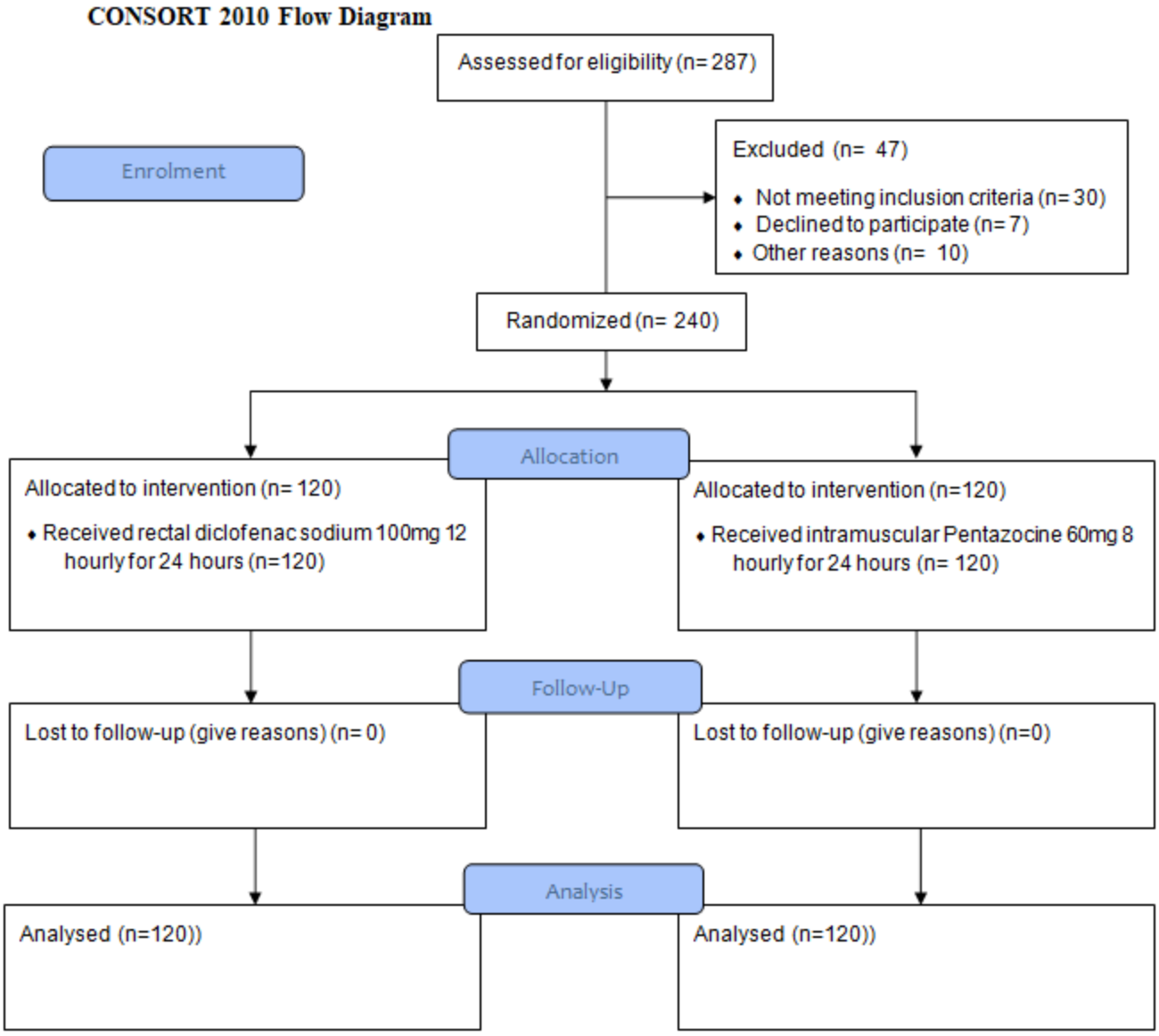
Study Drugs

The diclofenac sodium suppository used for the study was voltaren®, manufactured by Delpharm Huningue S.A.S., Huningue, France, for Novartis Pharma AG, Basel, Switzerland, a reputable pharmaceutical company with manufacturing date, expiry date, batch number and National Agency for Food and Drug Administration and Control (NAFDAC) registration number.

The parenteral pentazocine (pilat®) used was marketed by May and Baker Nigeria PLC, Ikeja, Lagos and manufactured by Belco Pharma, Bahadurgarh, Haryana, India, with the manufacture date, expiry date, batch number and NAFDAC registration number.

Visual analogue scale

The patient, in her own preferred language, was asked to mark a point on the scale that best indicates her perception of the pain severity using a marker pen. The assessment was done every 6 hours until 24 hours after surgery. Zero cm meant no pain, and 10 cm meant unbearable pain. Scores of 0-3 are interpreted as mild,



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 (https://pactr.samrc.ac.za).
Reporting was done according to the CONSORT checklist.

4-6 as moderate, while 7 and above as severe pain. The satisfaction of the women with the post-op analgesic used was assessed using a 5-point Likert scale. The possible responses could be 'very unsatisfied', 'unsatisfied', 'neutral', 'satisfied', or 'very satisfied'. She was asked if she could recommend the drug for others with a yes or no answer. She was observed for 48 hours post-op for possible side effects of the analgesic agents.

Method of Data Analysis

Data was cleaned and analyzed using SPSS version 26.0 (Microsoft, Chicago, IL, United States). The data was presented in tables and graphs as appropriate. The pain

Table 1: Socio-demographic characteristics of the study participants

Variables		*Rectal diclofenac*	*Injection pentazocine*	*Total*	*x2*	*df*	*p-value*
Age (years)	<20 years	0 (o,o)	1 (0.8)	1 (0.4)	3.237	5	0.657
	20–24	8 (6.6)	7 (5.8)	15 (6.3)			
	25–29	39 (32.2)	34 (28.1)	73(30.4)			
	30–34	45 (37.2)	43 (35.6)	88(35.7)			
	35–39	22 (18.2)	23 (19.0)	45 (18.8)			
	40–45	6 (5)	12 (10)	18 (7.5)			
Religion	Christianity	77 (64.2)	93 (77.5)	170 (70.8)	4.522	1	0.075
	Islam	43 (35.8)	27 (22.5)	70 (29.2)			
Education	None	4 (3.3)	3 (2.5)	7(2.9)	4.709	3	0.194
	Primary	12 (10)	4 (3.3)	16 (6.7)			
	Secondary	38 (31.7)	38 (31.7)	76 (31.7)			
	Tertiary	66 (55)	75 (62.5)	141 (58.8)			
Occupation	Civil servant	24 (20)	31 (25.8)	55 (22.9)	3.018	6	0.807
	Business	27 (22.5)	28 (23.3)	55 (22.90			
	Artisan	9 (7.5)	7 (5.8)	16 (6.70)			
	House wife	50 (41.7)	48 (40)	98 (40.8)			
	Unemployed	1 (0.8)	0 (0.0)	1 (0.40)			
	Student	6 (5)	3 (2.5)	9 (3.8)			
	farming	3 (2.5)	3 (2.5)	6 (2.5)			
marital status	Single	3 (2.5)	93 (77.5)	96(40.0)	1.145	2	0.565
	Married	116 (96.7)	27 (22.5)	143(59.6)			
	Divorced	1 (0.8)	0	1 (0.4)			

There was no significant difference in the socio-demographic characteristics between participants in both arms as shown in table one above

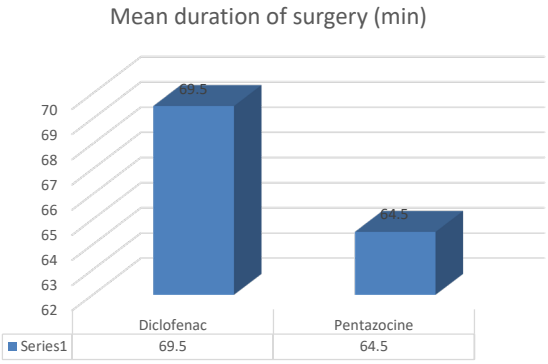


Figure 1: Standardized U-test 1.184; p-value=0.236

perception level (VAS) was presented as median and range and expressed as frequencies and percentages. Independent Samples Median test was used to compare the level of pain between the two groups, while the Pearson's Chi-square or Fisher's exact test was used to compare the maternal satisfaction and the side effects experienced in the two groups. All analyses were run at a 95% confidence level and a *p-value* of less than 0.05 was considered statistically significant.

Ethical Considerations

Ethical clearance for this study was obtained from the ethical committee of the hospital and written informed consent was obtained from the participants in accordance with the Helsinki declaration.

Conflict of Interest

There was no conflict of interest as the researcher was responsible for the cost of all reagents as well as other necessary materials. (VAS) and Likert's scale respectively

Limitations

Pain perception and maternal satisfaction are subjective; however, this subjectivity was minimized with the use of the Visual Analog Scale (VAS) and Likert's scale, respectively.

Results

All two hundred and forty (240) participants completed the study, with none lost to follow-up within the six months of the study. Reporting was done using the

Table 2: The obstetrics characteristics of both groups

Obstetric profile		*Rectal diclofenac*	*Injection pentazocine*	*Total*	*x2*	*df*	*p-value*
Parity	0	16 (13.3)	31 (25.8)	47 (19.6)	7	3	0.050
	1	31 (25.8)	35 (29.2)	66 (27.5)			
	2	63 (52.5)	47 (39.2))	110 (45.8)			
	5 & above	10 (8.3)	7 (5.8))	17 (7.10)			
Living children	0	30 (25.0)	42 (35.0)	72 ( )	5.528	3	0.137
	1	31 (23.8)	30 (25.0)	61 ( )			
	2	34 (28.3)	39 (32.5)	73 ( )			
	5 & above	5 (4.2)	9 (7.5)	14 ( )			
Gestational age	Pre term	26 (21.7)	22 (18.3)	48 (20.0)	1.334	3	0.7211
Age (years)	Early term	64 (53.3)	62 (51.7)	126 (52.5)			
	Full term	24 (20.0)	26 (21.7)	50 (20.8)			
	Post term	6 (5.0)	10 (8.3)	16 (6.7)			

The maternal obstetric characteristics of the participants are similar with no statistical significance between them.

Table 3: Level of pain experienced among the study participants

		Rectal Diclofenac	*injection Pentazocine*	*Total*	*x2*	*p-value*
6 hours	Mild	13 (10.8)	8 (6.7)	21 (8.8)	0.590	0.745
	Moderate	94 (78.3)	97 (80.8)	191 (79.6)		
	Severe	13 (10.8)	15 (12.5)	28 (11.6)		
	VAS (mean; min; max)	5.0,0.0,8.0)	5.0,0.0,8.0	5.0,0.0,8.0		
12 hours	Mild	20 (16.7)	12 (10)	32 (13.3)	2.702	0.259
	Moderate	90 (75.0)	94 (78.3)	184 (76.7)		
	Severe	10 (8.3)	14 (11.7)	24 (10.0)		
	VAS (mean ;min ;max)	4.0,0.0,8.0	5.0,0.0,7.0	5.0,0.0,8.0		
18 hours	Mild	36 (30.0)	24 (20.0)	60 (25.0)	4.959	0.084
	Moderate	81 (67.5)	88 (73.3)	169 (70.4)		
	Severe	3 (2.5)	8 (6.7)	11 (4.6)		
	VAS (mean ;min ;max)	4.0,0.0,7.0	4.0,0.0,7.0	4.0,0.0,10.0		
24 hours	Mild	55 (45.8)	40 (33.3)	95 (39.5)	4.030	0.122
	Moderate	63 (52.5)	78 (65.0)	141 (58.8		
	Severe	2 (1.7)	2 (1.7)	4 (2.7)		
	VAS (mean ;min; max)	4.0,0.0,7.0	4.0,0.0,8.0	4.0,0.0,8.9		

The majority of the participants had mild to moderate pain throughout the 24-hour period of the study, with most of the participants having moderate pain. The level of pain at 6 hours, 12 hours, 18 hours and 24 hours was similar in both groups. There was no statistical significance. (p =0.745, 0.259, 0.084 & 0.122, respectively).

Table 5: Maternal satisfaction

	Maternal satisfaction				
24 Hours post surgery	*Rectal diclofenac*	*Pentazocine*	*Total*	*X2*	*P-value*
Satisfied	116 (96.7%)	105 (87.5%)	221 (92.1)	5.712	0.017
Unsatisfied	4 (3.3%)	15 (12.5%)	19 (7.9)		

χ^{2t} represents chi-square with Yates' continuity correction, Significant at p<0.05

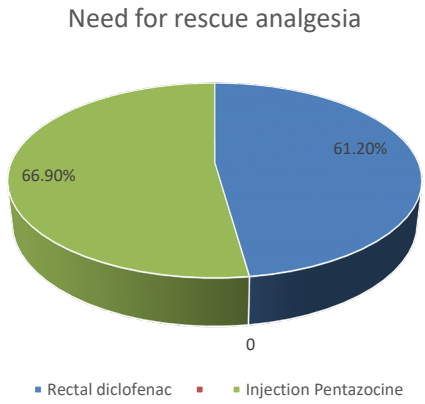


Figure 2: Need for rescue Analgesia

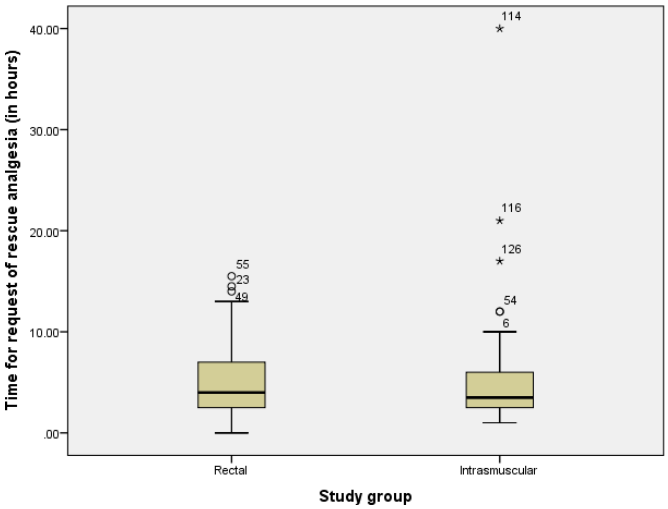


Figure 3: Standardized U-test = 0.479; *p-value* = 0.632
Standardized U-test = 0.563; *p-value* = 0.574

standard format for CONSORT 2010 for randomized controlled clinical trial guidelines.

The majority of the participants were within the ages of 30 to 34 years with 37.2% of them in the rectal diclofenac group and 35.6% in the intramuscular pentazocine group.

The duration of caesarean section in both groups is shown in Figure 1. These were similar in both groups. This was not statistically significant, $p = 0.236$.

In the rectal diclofenac group, 61.2% of the participants required rescue analgesia as against 66.9% in the intramuscular pentazocine group. This was not statistically significant, $p = 0.348$.

Participants in the rectal diclofenac group had an average of 4 hours to request rescue analgesia after the first dose of the drug, while that of the intramuscular Pentazocine group was 3.50 hours. The maximum and minimum number of hours to request rescue analgesia in the rectal diclofenac group were 0 and 15.50 hours, respectively, while it was I hour and 40 hours in the intramuscular pentazocine group. This was not statistically significant. Both groups had an average of one rescue analgesic used throughout the study period. The rectal diclofenac group had a minimum of 1rescue analgesia and a maximum of 4 rescue analgesia used in their group throughout the study period, compared to a minimum of 1 and a maximum of 6 used in the intramuscular pentazocine group. This was also not statistically significant $p = 0.574$.

The level of maternal satisfaction was higher in the rectal diclofenac group than the pentazocine arm at 24 hours post-operation when it was assessed. This was statistically significant $p = 0.017$. (p <0.05).

DISCUSSION

The socio-demographic and Obstetrics profiles of the women in both study groups are similar, as well as the indications for the caesarean sections. This similarity is important for any observed difference in the study outcome. Pain is one of the commonest morbidities following any surgical procedure, including caesarean section. Effective pain management is therefore an essential component of post-operative care, which can facilitate early ambulation and overall patient recovery. [2] This, in turn, will enhance early mother and baby bonding, regular and adequate breastfeeding, general wellbeing, and early return to her normal activities.[6] The analgesic effectiveness for the relief of post-caesarean section pain of both drugs is comparable, as most participants experienced mild to moderate pain in both groups; however, the visual analogue score was better in the diclofenac suppository group, though not statistically significant.

A similar study conducted in Nigeria and India by Uzoma *et al*[7] and Zulfiquar *et al*.,[8] respectively, also shows that rectal diclofenac was as effective as intramuscular pentazocine in the relief of post-caesarean section pain. The similarity in findings with both studies could be a result of similar doses and dosing intervals of the drugs used in the study. Onuora *et al* [9] also noted from their study that the difference in the analogue score was not statistically significant. Contrary to our finding, Rashid *et al*[10] observed that the difference in the mean level of post-caesarean section pain in the diclofenac rectal group after 24 hours using the analogue score was statistically significant compared to the intramuscular group (1.8 versus 3.7). The small sample size of 40 women in each arm in their study may have accounted for this difference from our study. Comparing the post-operative analgesic effect of rectal diclofenac with other analgesic drugs, Iribhogbe [11] and Sapkai *et al* [12] found that suppository diclofenac was more effective than intramuscular morphine and rectal glycerine, respectively. Rita *et al*[13] also compared 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. This study also reported lower pain scores with the suppository diclofenac group compared to the intramuscular pentazocine group, although not statistically significant. This study had a sample size of 150 divided into 3 groups.[14]

The time between the commencement of the drugs postoperatively and the time to demand for rescue analgesia in each group in this study and the number of rescue analgesia used in each group were comparable and not statistically significant, p = 0.632 and 0.574, respectively. Even though they were comparable, the time to demand rescue analgesia was longer in the rectal diclofenac group (a minimum of 4 hours) compared to the intramuscular pentazocine group (a minimum of 3 hours 50 minutes). This could be as a result of prolonged and steady absorption, providing continuous analgesia with the rectal route. 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*, Zulfaqar *et al* and Khan *et al* intheir respective studies.[8,9,14] This could be as a result of the same dose and similar dosing interval in their studies and the current study. This finding of fewer needs for rescue analgesia observed with the suppository diclofenac may be due to effective absorption from the rectal route as well as the prolonged continuous analgesic effect offered by the rectal route compared to the intramuscular route.

No significant side effects were noted in either group in this study, as the doses used were at recommended therapeutic doses. Five percent of the participants in each group reported some side effects, while 95% in each of the groupsdid not show any side effects. This indicates that suppository diclofenac sodium and intramuscular pentazocine administered for pain relief after caesarean section are safe. This was different from the findings of Uzoma *et al,* who did not find any side effects in the rectal diclofenac group, while 5 participants in the intramuscular group had side effects such as nausea, vomiting, headache and dizziness.[8] This could be as a result of the smaller sample size of 33 used in each group in their study, compared to 120 participants used in each group in the current study.

This study found a significant difference in maternal satisfaction between the 2 groups at 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,* which noted overall maternal satisfaction to be similar in the rectal and intramuscular group, and the study by Onuora *et al*.,[9] which did not find any difference in maternal satisfaction. Significant satisfaction with the suppository diclofenac may be due to the non-invasive nature during administration compared to the use of injections, which may, on its own, be painful.

Rectal diclofenac from this study has been shown to provide effective analgesia when given after caesarean section with a tolerable side/adverse effect profile. This will help to reduce the need for repeated injections, reduce financial burden, increase maternal morbidity and promote injection safety.

This current 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 differences 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 has shown that suppository diclofenac and intramuscular pentazocine are comparable in pain relief and need for rescue analgesia but diclofenac suppository shows better patient satisfaction when used for post-caesarean section pain relief.

References

1. Peter B, Maria Q, Sarah A, Ed J, Elizabeth A, Ursula B *et al*. Caesarean section surgical techniques: A randomized factorial trial (CAESAR). BJOG 2010;117:1366 76
2. Bamigboye AA, Hofmeyr JG. Caesarean section wound infiltration with local anaesthetic for post-operative pain relief any benefit? S Afr Med J 2010;100:313 9.
3. Adeniji AO, Atanda OO: Randomized comparison of effectiveness of unimodal opioid analgesia with multimodal analgesia in postcaesarean section pain management. J Pain Res; 2013, 6:419-424.
4. Jaykaran C, Tamoghna B. How to Calculate Sample Size for Different Study Designs in Medical Research. Indian journal of Psychological Medicine. 2013 Apr-Jun; 35(2): 121126. DOI: (10.4103/0253-7176.116232)
5. Obi OL, Tukur J, Abdurrahman A, Salisu I. A randomized controlled trial of rectal diclofenac sodium and intramuscular pentazocine versus intramuscular pentazocine, diclofenac and paracetamol analgesics for pain relief in the first 48hours after caesarean section. Trop J Obstet Gynaecol 2020: 37: 101-7. https://www.tjogonline.com/text.asp?2020/37/1/101/292286.
6. Shahraki AD, Jabalameli M, Ghaedi S. Pain relief after Caesarean section: Oral methadone vs. intramuscular pethidine. Res Med Sci 2012;17:143 7
7. Uzoma O, Adeniyi A, Bakare A, Oremole O, Adewara E, Okere R. *et al*. Rectal Versus Intramuscular Diclofenac Sodium for Pain Relief Following Caesarean section A Randomized Control trial. JMSCR. 2018; 6 (08): 624-630.
8. Zulfiqar M, Ashraf M, Khan MIH, Naeem F, Shakeel S. To compare efficacy of diclofenac by intramuscular route and rectal route in post-surgical pain. Professional Med J. 2021; 28(9):1269-75.
9. Onuorah CM, Fyneface-Ogan S, Aggo AT. The efficacy of diclofenac for post caesarean section analgesia: comparison of rectal and intramuscular routes. Nigerian journal of Medicine vol 27 No 3 (2018) DOI: 10.4103/1115-2613.278790
10. 10. Rashid M, Jaruidi HM. The use of rectal diclofenac for post Caesarean analgesia: Saudi medical journal 01 February 2000, 21(2): 145-149
11. Iribhogbe OI. Adjuvant rectal Diclofenac for Post-Operative pain control after caesarean section: A randomized controlled Trial. 2011. https://www.dssertation.npmcn.edu.ng.
12. Sapkai PS, Patil YD, Rajurkar SS. Use of rectal Diclofenac as an adjunct to spinal analgesia after caesarean section. Med Pulse International Journal od Anaesthesiology, Print ISSN:2579- 0900. Volume 6, issue 1 April 2018.
13. Rita D, Ujwala P, Pavithra K. Effect of injectable tramadol v/s diclofenac suppository in post-operative gynaecological patients. International journal of clinical obstetrics and gynaecology 2022;6(2):75-78.
14. Khan S, Majeed N, Ruqya A, Mehdi M, Safdar F, Bibj S. Comparison of analgesic efficacy of diclofenac suppository with intramuscular diclofenac in post-operative pain relief after caesarean delivery in the first 24 hours. JRMC 2022;26(4):642-648.