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Dexamethasone as an Adjuvant to Diclofenac and Acetaminophen for Post-Cesarean Pain Management: A randomized Placebo-Controlled Trial

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ABSTRACT

Background & Objective: The commonly used analgesia for post caesarean pain include combination regimens containing acetaminophen, non-steroidal anti-inflammatory agents (NSAIDs) and opioids. The objective of this study is inter alia to determine the effects of dexamethasone as adjuvant to commonly used NSAIDs for post-caesarean pain management.

Materials & Methods: One hundred and eighty-eight participants slated for caesarean delivery under spinal anesthesia were randomized into two groups of 94 participants each. One group received 2ml intravenous 8mg dexamethasone while the second group received 2ml of intravenous sterile water as placebo. Both groups received similar doses of intramuscular acetaminophen and diclofenac. Intramuscular pentazocine at a dose of 0.5mg/kg body weight was used as rescue analgesia. Primary outcome was the mean summed pain intensity difference (MDPID) in the two groups while the secondary outcomes include the needs and frequency of rescue analgesia, and the levels of maternal satisfaction. P-value set as ≤0.05.

Results: The mean summed pain intensity difference (MSPID) at 24hours post-caesarean was higher in the dexamethasone group, (29.27±18.10 versus 24.24±13.14, p=0.036). The percentage of the participants that required rescue analgesia in the dexamethasone group was less (60.6% versus 76.1%, p=0.024). The Overall levels of maternal satisfaction were comparable in both groups.

Conclusion: Intraoperative dexamethasone given intravenously as adjuvant to intramuscular diclofenac and acetaminophen minimizes opioid administration within the first 24hours after caesarean section.

Keywords: Acetaminophen, Adjuvant, Dexamethasone, Diclofenac, Post-Caesarean Pain

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Introduction

Cesarean section commonly induces moderate to severe pain for about 24 to 48 hours after the surgery (1). Acute postoperative pain is an undesirable outcome that can delay functional recovery of patients following surgery (2). Therefore, optimal perioperative pain management will not only allow the mother to ambulate early but also plays a key role in the postoperative rehabilitation, relief of suffering, shortened hospital stay, reduced hospital costs, increased maternal satisfaction and bonding between the newborn and the mother (3). While there are different protocols of postpartum pain management in women undergoing cesarean section (4), The Royal College of Anesthetists proposed standard for post cesarean section pain relief is that greater than 90% of women should have the worst pain score of less than 3cm on a visual analogue scale of 0-10cm (5), and that non-steroidal anti-inflammatory drugs should be prescribed to 100% of women and greater than 90% of women should be satisfied with pain management (6, 7). Multi-modal analgesia is currently recommended in the management of post-cesarean pain (3) which entails different drug combinations involving opioids, acetaminophen (paracetamol) and non-steroidal anti-

inflammatory drugs (NSAIDs). Darvish and colleagues **(8)**, found diclofenac and paracetamol combination to be more effective after cesarean section compared to meperidine an opioid, alone. Opioids are also associated with side effects such as nausea, vomiting, confusion, sedation, constipation, tolerance and physical dependency **(9, 10)**. Therefore, an opioid-sparing multimodal regimen will be preferred in the postoperative period to avoid unwarranted side effects of the opioids. Dexamethasone is a synthetic glucocorticoid with a powerful anti-inflammatory effect by acting on glucocorticoid receptors **(11)**. In addition, dexamethasone has antiemetic and analgesic properties when used as an adjuvant to potentiate non-steroidal anti-inflammatory agents and in peripheral nerve blockade **(12-15)**. This study was designed to determine the effects of intraoperative dexamethasone as adjuvant to intramuscular diclofenac and acetaminophen for post-cesarean pain management, with the following specific objectives;

1. To compare the Summed pain intensity difference (SPID) between the group that received dexamethasone and the group that received placebo as adjuvant to intramuscular diclofenac and acetaminophen for post-cesarean pain management.
2. To compare the proportion of participants that received rescue intramuscular pentazocine and the mean frequency of rescue analgesia used in the two groups.

To compare the levels of participants' satisfaction with their postoperative pain management in the two groups.

Methods

Study Design and settings

A randomized double-blinded placebo-controlled factorial trial conducted between January and July 2021 to determine the effects of single dose intravenous dexamethasone as an adjuvant to multiple doses of intramuscular diclofenac and acetaminophen for post-cesarean pain management at Federal Teaching Hospital, Ido-Ekiti, Ekiti State in the Southwestern Nigeria. The study was duly approved by the Health Research and Ethics Committee (HREC) of the institution with the approval number, ERC/2019/21/306A.

Study procedure

A total of 188 participants slated for elective or emergency cesarean delivery under spinal anesthesia with American society of Anesthesiologist (ASA) class I and II who consented for the study were included in the study. The exclusion criteria was women who had corticosteroids for enhancement of fetal lung maturity, those with any medical condition known to be potentially exacerbated by non-steroidal anti-inflammatory drugs such as peptic ulcer disease, pre-eclampsia and eclampsia, known adverse reactions or hypersensitivity to diclofenac, acetaminophen or pentazocine, any participants that will require special post-operative pain control such as women with sickle cell disease, gestational diabetes or overt diabetes. The women were randomized into two groups of 94 participants each. The study group received intravenous 8mg dexamethasone (2ml) after cutting of the umbilical cord while the control group received a placebo, intravenous 2ml of sterile water. Both groups received similar doses of intramuscular acetaminophen and diclofenac for postoperative pain management, according to the departmental protocol. Intramuscular pentazocine was used as rescue analgesia at a dose of 0.5mg/kg body weight (maximum of 60mg per dose) whenever the participants expressed moderate to severe pain (point 4cm and above on Visual Analogue Scale) after the baseline visual analogue scale pain assessment at 1 hour and the pain score repeated at 6 hours, 12 hours, 18 hours and 24 hours postoperative period. The time (in minutes) of administration of rescue analgesia were noted, and the number (frequency) of doses of rescue pentazocine administered to the women in the different study arms within the period of 24 hours after cesarean section were recorded.

Outcomes

Primary outcome is the mean summed pain intensity difference, SPID (which is derived by multiplying the PID score at each post-dose time point by the duration (hours) since the preceding time point and then summing the values over the 24 hours) in the two groups; while secondary outcomes include proportion of participants that received rescue pentazocine, mean frequency of rescue pentazocine and the levels of maternal satisfaction between the two groups. The postoperative pain was scored on a visual analogue scale as no pain when the participant marked 0cm, mild pain when the patient marked any point on the chart from greater than 0cm to 3cm, moderate pain when she marked any point from 4 to 6cm and severe pain on indication of any point from 7 to 10cm. The participants were asked to express their overall satisfaction with the postoperative pain management during the first 24 hours after surgery using a 5-point Likert scale **(16)** with options of very dissatisfied, dissatisfied, neutral, satisfied and very satisfied. Maternal basic characteristics such as the age, educational status, occupation, marital status, religion, tribe, maternal weight, height, antenatal booking status, type of cesarean sections, gestational age at delivery, gravidity and parity were entered into the proforma. Severity/intensity of pain was assessed and recorded at 1 hour after surgery as baseline, then at 6 hours, 12 hours, 18 hours and 24 hours postoperatively.

Sample Size Determination

The sample size was obtained based on the data from the pilot study conducted by the authors. In the pilot study, 20 women were recruited and randomized into

two groups (study and control) of 10 participants in each arm. Among other parameters, the mean and standard deviation (SD) of the summed pain intensity difference (SPID) were compared between the two groups.

Using the formula for calculation of minimum sample size for a comparative study; $n = 2(SD)^2 \times (Z_{\alpha/2} + Z_{\beta})^2/(d)^2$ (17). "SD" being the standard deviation of the mean SPID of the control group in a pilot study, and"d" being the effect size, the difference between the mean SPID of the treatment and control groups of the pilot study. With a study power of 80% and confidence interval of 95% and a 25% allowance for attrition, the calculated minimum sample size was 94 participants for each arm of the study.

Randomization Technique and blinding

The participants were randomly assigned to receive either intravenous 8mg (2ml) of dexamethasone (group 1) or 2ml of sterile water for injection (group 2) using a computer-(Microsoft Excel® program) generated list of random numbers of 1 to 188 in conjunction with a statistician that was not involved in the final data analysis. Following the generation of the random numbers using the 'RAND" function to capture the entire sample size of 188, another specialized Microsoft Excel program (ROUNDUP and IF D2 functions) was put into use to get the group assignments (Group 1 or Group 2). The list consisting of the randomization and group allocation was kept by a pharmacist who was also blinded to the study objectives. This pharmacist kept the sequentially numbered opaque and sealed envelopes in which the random numbers and group allocation were concealed in a locker in the pharmacist's room, with the key kept from unauthorized access. Whenever an eligible woman gave consent to participate in the study, the researcher or his assistant (a resident doctor on call) called the pharmacist on duty, who then opened the envelope corresponding to the participant's serial number and allocated her to the group concealed inside that particular envelope. The pharmacist then prepared the appropriate drug (be it 8mg dexamethasone or 2ml of sterile water for injection) in a 5ml syringe with similar appearance and sent it to the theater for administration to the participant, thus blinding the primary caregivers and the patient. The records of participant number and the drug received were kept and only unblinded for the final data analysis.

Statistical Analysis

The data and information obtained from this study were processed using International Business Machines Statistical Package for Social Sciences (IBM® SPSS Statistics, USA) for Windows software version 26. Frequency tables and Bar charts were made and results were tested for significance using non-parametric tests such as the Chi-square test or Fischer's exact test as appropriate, while continuous variables were presented as means with standard deviations and the difference were analyzed with student *t*-test, a parametric test. The level of significance set at $p \leq 0.05$.

Results

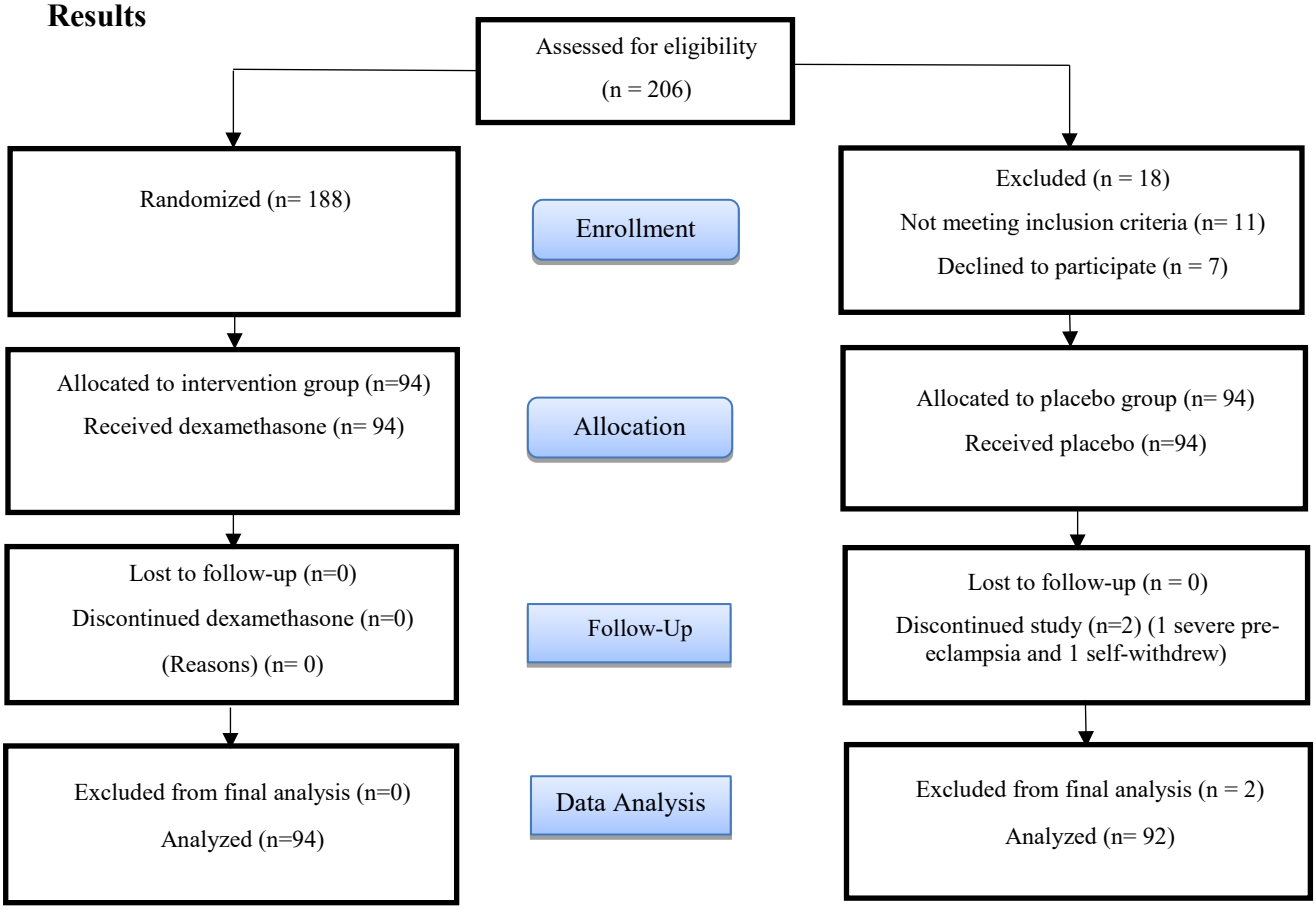


Figure 1. Participants' CONSORT Flow Diagram

All the 94 participants in the dexamethasone group completed their VAS scoring assessment, while 92 participants completed VAS scoring assessment in the control group. One woman in the control group developed severe pre-eclampsia four hours after delivery requiring intravenous magnesium sulfate and was dropped, while another woman, also in the control group, withdrew from the study six hours after surgery, as shown in CONSORT flow chart. Hence, VAS pain assessment was completed for the 92 participants in the control group. The characteristics of the study participants are shown in (Table 1a and 1b). There was no significant difference between the two groups in the basic socio-demographic (Table 1a) and obstetric characteristics (Table 1b)

Table 1a. Socio-demographic Characteristics of the participants

Characteristics	Dexamethasone Group	Control group	p-value
	N = 94	**N = 92**	
Age (years)			0.463
20 – 24	7 (7.4)	8 (8.7)	
25 – 29	15 (16.0)	20 (21.7)	
30 – 34	43 (45.7)	31 (33.7)	
35 – 39	17 (18.1)	16 (17.4)	
≥ 40	12 (12.8)	17 (18.5)	
Mean ± SD	32.5 ± *4.9*	32.7 ± 6.2	0.784
Range	20 – 42	20 – 44	
Educational status			0.643
Secondary	14 (14.9)	16 (17.4)	
Tertiary	80 (85.1)	76 (82.6)	
Occupation			0.568
Civil servants	56 (59.6)	48 (52.2)	
Artisan	8 (8.5)	6 (6.5)	
Traders	24 (25.5)	32 (34.8)	
Housewives, unemployed	6 (6.4)	6 (6.5)	
Marital status			0.525
Single	5 (5.3)	7 (7.6)	
Married	89 (94.7)	85 (92.4)	
Religion			0.586
Christianity	86 (91.5)	82 (89.1)	
Islam	8 (8.5)	10 (10.9)	
Tribe			0.520

Characteristics	Dexamethasone Group	Control group	p-value
Yoruba	82 (87.2)	83 (90.2)	
Others	12 (12.8)	9 (9.8)	

***Student's t-test; χ2 =Chi-square test.**

Table 1b. Basic clinical and obstetric Characteristics of participants

Characteristics	Dexamethasone Group	Control group	P-value
	N = 94	**N = 92**	
Maternal weight (Kg)			
Mean ± SD	76.8 ± 7.9	76.3 ± *9.7*	0.729
Range (Min – Max)	61 – 87	55 – 88	
Maternal Height (m) Mean ± SD	1.60 ± 0.08	1.58 ± 0.08	0.112
Range (Min – Max)	1.42 – 1.85	1.40 – 1.89	
Antenatal Booking *n (%)*			0.458
Booked	78 (83.0)	72 (78.3)	
Unbooked	16 (17.0)	20 (21.7)	
Type of Caesarean section			0.661
Elective	49 (52.1)	52 (56.5)	
Emergency	45 (47.9)	40 (43.5)	
Gestational age(weeks)			
Mean ± SD	38.1 ± 1.4	37.7 ± 2.4	0.164
Range (Min – Max)	30 – 41	35 – 41	
Gravidity *n (%)*			0.830
Primigravidae	11 (11.7)	12 (13.0)	
Multigravidae	83 (88.3)	80 (87.0)	
Mean ± SD	3.05 ± 1.47	3.08 ± 1.54	0.917
Range (Min – Max)	1 – 7	1 – 8	
Parity *n (%)*			0.792
Nulliparous	14 (14.9)	16 (17.4)	
Primiparae	22 (23.4)	26 (28.3)	
Multiparae	50 (53.2)	43 (46.7)	
Grand multiparous	8 (8.5)	7 (7.6)	
Mean ± SD	2.55 ± 0.85	2.45 ± 0.87	0.395
Range (Min – Max)	0 – 6	0 – 7	

χ2 =Chi-square test; t-test=Student's t-test

(Table 2) shows the Summed pain intensity difference (SPID) between the two groups over the first 24 hours after surgery. There is a statistically significant difference in the SPID at 18th hour and 24thhours between the dexamethasone and control groups with p value of 0.009 and 0.038, respectively. Also, mean SPID $_{at}$ 24 hours, which is the primary efficacy endpoint (primary measure) over a period of 24 hours post-cesarean section, was higher in the dexamethasone group than the control group (29.27±18.10 vs. 24.24±13.14, p=0.036).

Table 2. Comparison of Summed Pain Intensity between the two groups

Outcome	Dexamethasone group (N = 94)	Control group (N = 92)	p-value
SPID 6thhr **Mean ± SD** **Range (Min – Max)**	8.21 ± 6.24 0.00 – 21.00	7.81 ± 5.83 0.00 – 29.27	0.654
SPID 12thhr **Mean ± SD** **Range (Min – Max)**	8.75 ± 7.49 0.00 – 24.60	7.71 ± 6.28 0.00 – 26.40	0.300
SPID 18thhr **Mean ± SD** **Range (Min – Max)**	7.25 ± 6.27 0.00 – 26.40	5.11 ± 4.63 0.00 – 21.60	0.009
SPID 24thhr **Mean ± SD** **Range (Min – Max)**	5.11 ± 5.46 0.0 – 24.00	3.62 ± 3.78 0.00 – 16.80	0.038
SPID 24 hours			
Mean ± SD **Range (Min – Max)**	29.27 ± 18.10 2.20 – 77.30	24.24 ± 13.14 6.40 – 84.10	0.036

SPID (Time weighted) = Summed Pain Intensity Difference, t-test=Student's t-test.

(Table 3) shows that there was a statistically significant difference in the requirement for rescue analgesia between the dexamethasone and control groups (60.6% vs. 76.1% respectively, p=0.024). Also, the time to the first administration of rescue analgesic medication was longer with a statistically significant difference in the dexamethasone than control groups (time in minutes: 386.0± 222.9 vs. 314.6± 179.5 respectively, p=0.048). There was a statistically significant difference in the mean frequency (mean total use) of rescue analgesic use between the dexamethasone and control groups (1.63±0.72 vs. 1.89±0.75 respectively, p=0.037).

Table 3. Comparison of Time to first dose and mean frequency of Rescue analgesia

Variables	Dexamethasone Group	Control group	p-value
Rescue analgesia administered	N = 94(%)	N = 92(%)	
Yes`	57 (60.6)	70 (76.1)	0.024
No	37 (39.4)	22 (23.9)	
Time to first rescue analgesia (mins)	n = 57	n = 70	
Mean ± SD	386.0 ± 222.9	314.6 ± 179.5	0.048
Range (Min – Max)	64.0 – 1088.0	9.0 – 1086.0	
Mean frequency of rescue analgesia	n = 57	n = 70	
Mean ± SD	1.63 ± 0.72	1.89 ± 0.75	0.037
Range (Min – Max)	1.00 – 3.00	1.00 – 4.00	

***** Chi-square test; t-test=Student's t-test.***

(Table 4) shows the side effect profile of the participants in the two groups. No woman reported any adverse effect during the period of the study. The side effect profile favored the dexamethasone group compared with the control. Women in the dexamethasone group reported the least side effect of nausea (8.5%), vomiting (3.2%), sedation (9.6%), and headache (11.7%) as against 19.6%, 8.7%, 16.3% and 25.0%, respectively in the control group. However, the difference is statistically significant only for nausea and headache with p-value of 0.030 and 0.019, respectively.

Table 4. Comparison of Side Effect profile of medications used between the two groups

Side Effects	Dexamethasone group n (%)	Control group n (%)	p-value
	N = 94	N = 92	
Nausea	8 (8.5)	18 (19.6)	0.030
Vomiting	3 (3.2)	8 (8.7)	0.112
Sedation	9 (9.6)	15 (16.3)	0.171
Headache	1 1(11.7)	23 (25.0)	0.019
Others	2 (2.1)	6 (6.5)	0.140

χ2 =Chi-square test.

(Figure 1) is a bar chart showing the maternal expression of satisfaction at 24 hours postoperative period in the two groups of participants using a 5-point Likert scale. This shows that there was a similar level of satisfaction in the dexamethasone group and control group with very satisfied being 46.8% vs. 31.5%, satisfied being 52.1% vs. 64.1% and neutral being 1.1% vs. 4.4% respectively and these were not statistically significant, p=0.055.

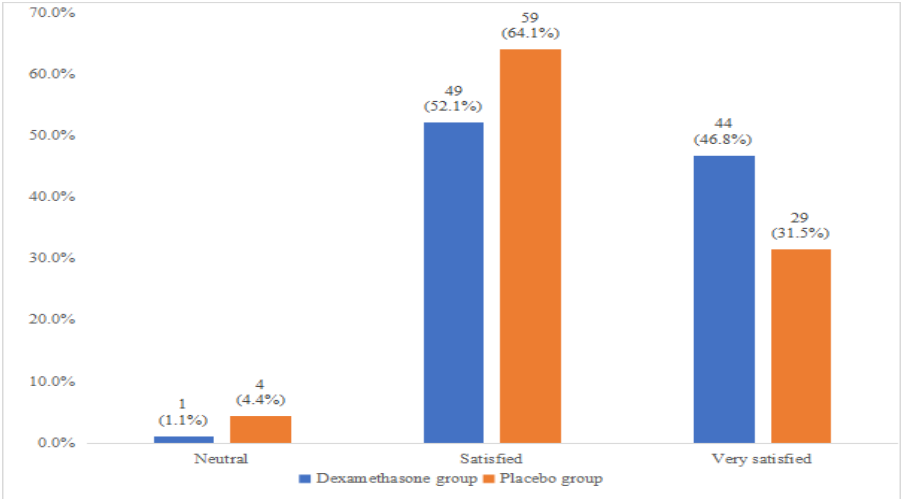


Figure 2. Maternal expression of satisfaction (X2 = 5.787, p = 0.055)

χ2 =Chi-square test

Discussion

This study shows improved post-operative pain management in women who had intraoperative administration of intravenous 8mg dexamethasone as adjuvant to intramuscular diclofenac and acetaminophen for post-cesarean section pain relief compared to the control group. The finding from this study was in agreement with previous studies where single dose dexamethasone was effective as an adjuvant in post-operative pain relief compared with placebo **(13, 14)**. The mean age of participants in both

groups falls within the reproductive age bracket and was comparable to that of Cardoso and colleagues **(18)**. The majority of the participants are Yoruba, Christians and civil servants, which is a reflection of the study location being in the South-west region of Nigeria **(19)**. The Obstetric characteristics are similar to the finding in a study of post-operative pain management after cesarean section in Nigeria **(20)**. The mean SPID over 24 hours period after the cesarean section derived by multiplying the PID score at each post-dose time point by the duration (hours) since the preceding time point and then summing the values over the 24 hours was noted to be higher in the dexamethasone group than the control group (29.27±18.10 vs. 24.24±13.14, p=0.036). This higher mean SPID in the dexamethasone group compared to the control group is statistically significant, and similar results (higher SPID) were obtained from other studies that assessed postoperative pain **(21, 22)**. This study also revealed that rescue medication in the form of intramuscular pentazocine was administered less frequently in the dexamethasone group than the control group (57 vs. 70, p=0.024 which constitutes 60.6% and 76.1%). This is similar to findings in other studies in which rescue opioid analgesia was used more in the control group than the dexamethasone group **(23-26)**. Ayu, et al. **(24)** found that administration of opioid at the 6th hour was performed in 71.4% of only paracetamol group, compared to 28.6% in the paracetamol-dexamethasone group following cesarean section. Our finding is also similar to that of Maged, et al. **(25)** on cesarean section patients, which concluded that administering intravenous dexamethasone reduces total opioid requirement in the first 24 hours postoperatively. However, our result contrast to finding from a study done by Nanji, et al. **(15)** who found no difference in opioid administration between the study drug and control group though lower dose of 4mg dexamethasone was used in their study. In our study, the mean time (in minutes) to the first dose of rescue medication was found to be longer in the dexamethasone group compared to the control group (386.0±222.9 vs. 314.6±179.5, p=0.048). This is statistically significant with similar findings noted in other studies **(27, 28)**. However, Parthasarathy and colleagues in India found a shorter mean time to the first dose of rescue analgesic of 3 hours (180 minutes) for the dexamethasone group and 6.6hours (396 minutes) for the control group with p value <0.001, despite using the same dose of intravenous 8mg dexamethasone similar to our study **(23)**. The disparity may be due to the smaller sample size of 60 patients recruited compared to the larger sample size of 188 participants in our study. Also, methodological approach of assessing the severity of pain more frequently (eight times in the recovery room and five times in the postoperative ward) and at shorter intervals of 0, 15, 30, 60, 90, 120, 150, 180 minutes and 4, 5, 6, 12, and 24 hours postoperatively might have made pain perception to be detected faster and earlier, thus making the first dose of rescue analgesic to be administered earlier in their study than in our study where pain severity was assessed only 5 times at 1, 6, 12, 18, and 24 hours post-cesarean section. The mean frequency of rescue analgesic medication was also found to be significantly reduced in the dexamethasone group compared to the control group in this study (1.63±0.73 vs. 1.89±0.75, p=0.037). This is similar to findings by Shalu, et al. **(29)** who observed reduction in the total dose of tramadol requirement in the dexamethasone group in the first 24 hours after surgery.

This study reported a lower profile of side effects in the dexamethasone group compared to the control group. This may be attributable to the mechanism of action of the drug, as it inhibits acute inflammation and might lead to reduced irritation of the upper gastro-intestinal system. The side effects in the dexamethasone group versus the control group in this study were nausea (8.5% vs. 19.6%, p= 0.030), vomiting (3.2% vs. 8.7%, p=0.112), sedation (9.6% vs. 16.3%, p=0.171), and headache (11.7% vs. 25.0%, p=0.019). These findings support previous findings where dexamethasone administration was associated with reduced side effects **(18, 23, 28)**. However, Shahraki, et al. **(14)** reported no significant difference in the postoperative nausea and vomiting between the treatment and the control groups. The authors, however, used morphine as rescue analgesia in that study as against pentazocine in our study. Incidence of sedation was observed to be reduced in the dexamethasone group compared with the control group in our study (9.6% vs. 16.3%) though this did not assume statistical significance. Shalu and Ghodki **(29)** also did not record statistical difference in this side effect in their study. The reduced incidence of post dural puncture headache in the dexamethasone group in this study (11.7% vs. 25.0%, p=0.019), is similar to findings by Hamzei, et al. **(30)** at Bahman Hospital, Iran, where that reported incidence of 2.5% vs 12.5% (p=0.016) for dexamethasone and the control groups respectively in the first 24 hours post-cesarean. This is in contrast to the study by Yang and colleagues that found no protective effect against postural puncture headache in the first 24 hours after cesarean section when prophylactic 8mg dexamethasone was administered **(31)**.

The overall satisfaction of the participants with postoperative pain management is similar in both study groups. This may be attributable to the effective multimodal analgesic regimen of diclofenac, acetaminophen and rescue pentazocine used in this study. This finding was consistent with previous studies in which multimodal analgesic regimens were used for post-cesarean section pain management by Egede, et al. **(10)** in Nigeria that reported no significant difference in patient satisfaction. These findings are, however, in contrast to the study by Shahraki, et al. **(14)** that showed a statistically significant difference (p=<0.001) between groups in terms of level of satisfaction, which might be due to the methodological

approach to the postoperative pain management in which morphine was solely administered rather than multimodal analgesic regimen as explored in our study and other cited studies for post-cesarean section pain control.

Limitations

Pain threshold and perception are very subjective, which definitely might have affected the interpretation of the results in this study. Also, a longer postoperative period and large multicenter studies would give a broader insight into the role of dexamethasone in post-cesarean section pain management.

Conclusion

The women in the dexamethasone group had better analgesic effects, reduced opioid administration and reduced side effect profile during the first 24 hours postoperative period. Also, the levels of satisfaction with the postoperative pain management were comparable between the dexamethasone and the control groups. The findings in this study suggest that the use of dexamethasone as an adjuvant may advance the management of post-operative pain in women following cesarean sections.

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Authors' Contributions

Adebisi MO, Adeniyi AA, Adeyemo OT, Orewole OT conceived and designed the study. Adebisi MO, Adekanye EA, Afolabi BO collected the data. Adewara EO, Adebara IO, Awoyinka BS, Bakare A contributed data. Adebisi MO, Adeniyi AA analyzed the data. Adebisi MO, Adeniyi AA, Adeyemo OT, Orewole OT, Adekanye wrote the paper, while all authors reviewed the paper.

Conflict of Interest

The authors declared no conflict of interest.

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