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Original Article

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Pentazocine Alone Versus Pentazocine Plus Diclofenac for Pain Relief in the First 24 Hours after Caesarean Section: A Randomized Controlled Study

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ABSTRACT

Introduction: Postoperative pain is one of the main postoperative adverse outcomes following caesarean section. Its management still remains a challenge especially in a low resource setting.

Aim: To compare the efficacy of intramuscular pentazocine alone and combined intramuscular pentazocine with diclofenac for pain relief within 24 hours after caesarean section.

Materials and Methods: This was a double blind randomized control study of post caesarean section pain management of 140 participants between April and December, 2015 at the Federal Teaching hospital, Abakaliki. Inclusion criteria involved consenting and low risk parturients who had caesarean section under spinal anaesthesia. The participants were randomly grouped into Pentazocine-Placebo (PP) group and Pentazocine-Diclofenac (PD) group. The PP group received pentazocine 30 mg every 4 hours for 24 hours and 3 milliliters of water for injection as placebo 12 hourly for 24 hours while the PD group received pentazocine 30 mg every 4 hours and diclofenac 75 mg every 12 hours for 24 hours. The level of pain control was assessed using the Visual Analog Scale (VAS). The data was analysed with IBM SPSS version 20.0. The level of significance was set at < 0.05.

Results: The use of PD for 24 hour post caesarean section analgesia achieved better pain relief, faster onset of postoperative ambulation, bowel sound auscultation and oral feeding than the use of PP (p-value ≤ 0.002). However, the use of PD is more expensive than PP (p-value $=0.0001$). There was no difference between the two groups of participants on the passage of flatus and duration of hospital stay (p-value ≥ 0.05). The use of PP was associated with more maternal side effects (p-value=0.009). There was no difference on the level of satisfaction between the two groups of participants (p-value ≥ 0.05).

Conclusion: The use of PD for post caesarean section analgesia is more effective in achieving a satisfactory pain relief and has less side effects.

Keywords: Multimodal analgesia, Nigeria, Post caesarean section, Unimodal analgesia

INTRODUCTION

Caesarean section represents the most significant operative intervention in obstetrics and has saved lives of many mothers and infants [1]. The rate has been on the increase as a result of better surgical techniques, improvement in the intraoperative anaesthesia, availability of blood for transfusion and antibiotics and other social reasons including client's request for non-medical reasons [2]. The rate varies from country to country and between institutions. Globally, the rate varies between 10% and 35% in most developed countries [2,3]. In Nigeria, the caesarean section rate varies between 18.5% and 35.9% [4-8]. There is a high aversion for surgeries, with morbid fear for death and pain during and after surgeries in this environment [9]. Pain during and after caesarean section was the greatest concern in about 20% of parturients who were asked about their fears and expectations during caesarean section [10,11]. Therefore, postoperative pain management is as important as the pre and intraoperative care and may influence future health seeking behaviour of the patients.

Postoperative pain is one of the main postoperative adverse outcomes causing distress to patients [12]. It 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 [13,14]. This is even worse in obstetrics where post caesarean section pain may interfere with ambulation, breastfeeding, and early maternal bonding with the infant. Postoperative pain might lead to thrombo-embolic events, uterine sub-involution and post-partum haemorrhage as well as stress on the health care system [12,14,15]. It could also lead to psychological and emotional distress. Thus, it seems that postoperative pain management of patients within the immediate puerperium is more challenging than other surgical patients [15-17].

In sub-Saharan Africa, drug availability and cost has remained an important consideration in the choice of postoperative analgesia. At the study centre, there is no consensus on post caesarean section analgesia among the obstetricians thereby making them to use different methods. Though many obstetricians use opioid analgesics, they are associated with complications such as ventilatory depression, sedation, postoperative nausea and vomiting, pruritus, difficulty in voiding and ileus [18-20]. More so, Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) are associated with bleeding, platelet dysfunction and renal insufficiency. With knowledge of these complications, some obstetricians prefer the use of only opioids as post caesarean section analgesia. However, studies have shown that multimodal analgesia involving opioids and NSAIDs combination is associated with fewer side effects [9,10]. This lack of consensus may have some consequences not only on the patients but also on the health facility. Therefore effective management of post caesarean section pain in this environment still poses some unique challenges. From medline search, there is a paucity of studies on this subject matter in Nigeria and in South-East Nigeria in particular. This study was aimed at comparing the effectiveness of pentazocine alone versus

combined pentazocine with diclofenac as pain relief within 24 hours post caesarean section.

MATERIALS AND METHODS

Abakaliki is the capital of Ebonyi State, a mainland south-eastern state of Nigeria. Urban Abakaliki consists of two local government areas, namely Abakaliki and Ebonyi, out of 13 local government areas in Ebonyi State. The Federal Teaching Hospital (FETHA) is a tertiary hospital located in Abakaliki metropolis. The hospital is the merger between the former Ebonyi State University Teaching Hospital and the Federal Medical Centre, Abakaliki. The hospital gets referrals from within Ebonyi State and the neighbouring states of Enugu, Abia, Imo, Cross River and Benue.

This was a double blind randomized control study of pain management of uncomplicated caesarean section cases between April 1 and December 31, 2015. Initially, computer generated random numbers were collated and each number was sealed in a brown envelope. Each number was coded with a particular drug: either placebo (3 milliliters of sterile water for injection) or diclofenac and each participant chose a number that corresponded with the one in the envelope. All the participants received pentazocine (Penzor manufactured by Elyzium pharmaceutical Limited, India) 30 mg 4 hourly for 24 hours. In addition each participant received injection of either placebo (3 milliliters of sterile water for injection) 12 hourly for 24 hours or diclofenac (Olfen-75 manufactured by Merkel, Blaubeuren-Weiler Germany) 75 mg 12 hourly for 24 hours. All the drugs were administered by intramuscular route and each patient was treated along the line of packed analgesic as stated.

The sample size for the study (N) was calculated using the formula [21]:

$N= (U+V)^2 \{P_1 (1-P_1) +P_2 (1-P_2)\}/(P_1-P_2)^2$ where U was power at 90%, V was confidence interval at 95% and it was 1.96; P_1 was expected patient satisfaction using combined pentazocine and diclofenac analgesics and a previous study showed a 90% satisfaction [22]. P_2 was expected patient satisfaction using pentazocine only analgesic and the same study showed a 70% satisfaction [22]. Adding a 10% attrition rate, the sample size for each of the groups was 67.

Inclusion criteria involved consenting low risk parturients who had either elective or emergency caesarean section, under spinal anaesthesia, who were fully conscious at FETHA, Abakaliki, Ebonyi, Nigeria. However, the exclusion criteria comprised the parturients who had caesarean section under general anaesthesia, had stillbirth or history of allergy to pentazocine or diclofenac. Also, excluded were the parturients with history of severe obstetric haemorrhage, delirium, preexisting opioid dependency, sickle cell haemoglobinopathy, peptic ulcer disease, psychiatric illness, illiteracy and those that declined consent to participate in the study despite adequate counselling. The consent to participate in the study was obtained from the eligible participants before the caesarean section.

The agents for the study were administered within one hour after the surgery, according to the group each of the parturients belongs. The primary outcome measure was postoperative pain control, while the secondary outcome measures comprised patient satisfaction and maternal and neonatal adverse outcomes. Pain control was assessed using a VAS [23]. Each participant was taught on how to use the VAS at enrolment prior to the surgery. Score of 1-4 was classified as mild pain, 5 to 8 as moderate pain and above 8 as severe pain. Trained research assistants and the investigators undertook the assessment at the 1st, 2nd, 6th, 12th, 18th and 24th hour after the surgery. The side effects of the drugs, such as drowsiness, nausea and vomiting (in the mothers) and excessive sleeping (in the newborns), were also noted. Additional dose of pentazocine was used as break through analgesic at patient's request or when the VAS was > 6.

The information obtained was entered into a predesigned data sheet. The social class of the participants was calculated using the classification by Olusanya O and his co-authors [24]. The data was analysed with Statistical package for Social Sciences (IBM SPSS Inc, Chicago, IL, USA) version 20.0. Categorical variables were analysed using the Pearson chi square test while the continuous variables were analysed using the student's t-test. The level of significance was set at < 0.05. The ethical clearance for this study was obtained from the Ethics Committee of FETHA. This manuscript adheres to the applicable equator guidelines.

RESULTS

A total of 146 parturients who had uncomplicated caesarean section participated in the study. However, it was only 140 (95.9%) of them who made the inclusion criteria that were analysed and 70 of them were in each group. Six of the parturients opted out in the course of the study. [Table/Fig-1] contains the socio-demographic characteristics of the participants. There was no statistical significant difference between the 2 groups of participants on the variables. The distribution of the type of surgery among the participants is contained in [Table/Fig-2]. There was no statistical significant difference between the participants who received the PP and those who received PD on the types of surgery performed on them. [Table/Fig-3] contains the mean parity, age, gestational age

Level of Education	Pentazocine (%)	Pentazocine Diclofenac (%)	Total (%)	χ^2	p-value
Primary	2(2.9)	3 (4.3)	5(3.6)	0.270	0.874
Secondary	38(54.3)	36(51.4)	74(52.9)		
Tertiary	30(42.9)	31(44.3)	61(43.6)		
Total (%)	70 (100)	70(100)	140(100)		
Tribe				7.610	0.179
Igbo	67 (95.7)	69(98.6)	136(97.1)		
Others	3 (4.3)	1(1.4)	4(2.8)		
Total (%)	70(100)	70(100)	140(100)		
Religion				0.581	0.901
Catholic	50(71.4)	49(70.0)	99(70.7)		
Protestants	9(12.9)	11(15.7)	20(14.3)		
Pentecostal	11(15.7)	10(14.3)	21(15.0)		
Total	70(100)	70(100)	140(100)		
Social Class				2.311	0.679
1	12(17.1)	10(14.3)	22(15.7)		
2	17(24.3)	21(30.3)	38(27.1)		
3	32(45.7)	31(44.3)	63(45.0)		
4	8(11.4)	5(7.1)	13(9.3%)		
5	1(1.4)	3(4.3)	4(2.9)		
Total	70(100)	70(100)	140(100)		
Booking Status				0.282	0.595
Booked	63(68.6)	61(87.1)	124(88.6)		
Unbooked	7(10.0)	9(12.9)	16(11.4)		
Total (100)	70(100)	70(100)	140(100)		

[Table/Fig-1]: Social demographic variables of the participants.

Type of Surgery	Pentazocine (%)	Pentazocine Diclofenac (%)	Total	χ^2	p-value
Elective	44 (62.9)	46 (65.7)	90	0.124	0.724
Emergency	26(37.1)	24 (34.3%)	50		
Total	70 (100)	70 (100)	140		
Primary	45(64.3)	51(72.9)	96	1.193	0.275
Previous	25(35.7)	19(27.1)	44		
Total	70(100)	70(100)	140		

[Table/Fig-2]: The distribution of the type of surgery among the participants.

Variable	Group (N=70)	Mean (±SD)	t	p-value	95% Confidence interval of the difference
Age (yr)	Pentazocine-Placebo	30.69±1.26	0.552	0.582	-0.996 to 1.768
	Pentazocine-Diclofenac	30.30±1.16			
Parity	Pentazocine-Placebo	2.87±1.56	0.582	0.562	-0.377 to 0.691
	Pentazocine-Diclofenac	2.71±1.55			
Gestational age (wk)	Pentazocine-Placebo	39.08±1.80	-2.006	0.47	-10.213 to -0.72
	Pentazocine-Diclofenac	40.09±2.67			
Duration of surgery (min)	Pentazocine-Placebo	63.10±12.29	1.058	0.292	-1.925 to 6.354
	Pentazocine-Diclofenac	60.89±12.47			
Estimated blood loss (ml)	Pentazocine-Placebo	482.86±97.76	0.991	0.324	-16.359 to 49.216
	Pentazocine-Diclofenac	466.43±98.44			

[Table/Fig-3]: Mean parity, age and gestational age of delivery, estimated blood loss and duration of surgery among the participants.

at delivery, estimated blood loss and duration of surgery among the participants. Also there was no statistical significant difference between the two groups of participants on these variables.

[Table/Fig-4] shows the mean pain scores and duration of activities of the participants. The use of PD for 24 hour post caesarean section analgesia achieved better pain relief than the use of PP (p-value ≤0.002). When compared with PP, the use of PD for 24 hour post caesarean section analgesia showed faster onset of postoperative ambulation, bowel sound auscultation and onset of oral feeding (p-value=0.001). However, there was no statistical significant difference between the 2 groups of patients on the passage of flatus and duration of hospital stay (p-value ≥0.05). The maternal and newborn side effects of the drugs among the participants are contained in [Table/Fig-5]. There were significant side effects associated with PP when compared with PD on post caesarean section analgesia (p-value=0.009). [Table/Fig-6] contains the comparison of level of satisfaction among the participants. There was no statistical significant difference on the level of satisfaction between the participants on PP and those on PD (p-value ≥0.05). [Table/Fig-7] contains the comparison of the cost of post caesarean section analgesia. The combined use of pentazocine and diclofenac was significantly more expensive than pentazocine alone for post caesarean section analgesia (p-value=0.0001).

Variable	Group (N=70 each)	Mean (±SD)	t	p-value	95% confidence interval of the difference
1st Hour VAS	PP	5.01±1.64	8.782	0.001	1.782 to 2.818
	PD	2.91±1.45			
2nd Hour VAS	PP	4.13±1.76	6.217	0.001	1.120 to 2.165
	PD	2.49±1.34			
6th Hour VAS	PP	3.56±1.86	5.568	0.001	0.958 to 2.013
	PD	2.07±1.23			
12th Hour VAS	PP	2.83±1.14	8.369	0.001	1.091 to 1.766
	PD	1.40±0.86			
18th Hour VAS	PP	1.96±0.84	4.168	0.001	0.360 to 1.011
	PD	1.27±1.09			
24th Hour VAS	PP	1.50±0.79	3.222	0.002	0.171 to 0.715
	PD	1.06±0.83			
Duration from surgery to ambulation (Hours)	PP	19.97±2.51	3.105	0.001	0.69299 to 2.22129
	PD	18.61±2.49			
Duration from surgery to flatus passage (Hours)	PP	18.63±2.14	0.182	0.856	-0.70546 to 0.84847
	PD	18.56±2.49			
Duration from surgery to the presence of bowel sound on auscultation (Hours)	PP	11.60±2.32	5.549	0.001	1.25973 to 2.70855
	PD	9.64±1.82			
Duration of surgery to oral feeding(Hours)	PP	22.14±3.07	3.738	0.001	0.83430 to 2.70855
	PD	20.37±2.50			
Duration of hospitalization (Hours)	PP	6.57±1.26	2.371	0.19	0.8072 to 0.89071
	PD	6.09±1.16			

[Table/Fig-4]: Mean pain scores and duration of activities among the participants.
Note: PP = Pentazocine-Placebo, PD = Pentazocine-Diclofenac, SD = Standard deviation

Side effects / Maternal	Pentazocine (%)	Pentazocine diclofenac (%)	Total	χ^2	p-value
Drowsiness	17(24.3)	6(8.6)	23	9.325	0.009
Nausea	6(8.6)	2(2.9)	8		
None	47(67.1)	62(88.6)	109		
Total	70(100)	70(100)	140		
Newborn				0.000	1.000
Excessive sleep	2(2.9)	2(2.9)	4		
None	68(97.1)	68(97.1)	136		
Total	70	70	140		

[Table/Fig-5]: Maternal and newborn side effects of the drugs among the participants.

Variable	Level of Satisfaction		Total	χ^2	p-value
	Unsatisfied	Satisfied			
Pentazocine	16(12.9%)	54(77.1%)	70	2.386	0.122
Pentazocine diclofenac	9(12.9%)	61(87.1%)	70		
Total	25	115	140		
Primary CS	16(16.7%)	80(83.3%)	96	0.295	0.587
Repeat CS	9(20.5%)	35(79.5%)	44		
Total	25	115	140		
Emergency	12(24.0%)	38(76.0%)	50	2.001	0.157
Elective	13(14.4%)	77(85.6%)	90		
Total	25	115	140		
Booked	20(16.1%)	104(83.9%)	124	2.209	0.164
Unbooked	5(31.2)	11(68.9%)	16		
Total	25	115	140		

[Table/Fig-6]: Comparison of level of satisfaction among the participants.

Drugs	Total dosage	Cost (Naira)	PD	PP	χ^2	p-value
Pentazocine	6	600	1000	600	317.87	0.0001
Diclofenac	2	400				

[Table/Fig-7]: Comparison of the cost of post caesarean analgesia.
PP= Pentazocine- Placebo; PD=Pentazocine-Diclofenac

DISCUSSION

This study has shown that though, the combined use of pentazocine and diclofenac for 24 hour post caesarean section analgesia was more expensive, it achieved better pain relief and faster onset of postoperative ambulation, bowel sound auscultation and oral feeding than the use of pentazocine alone (p-value ≤0.002). There were significant maternal side effects associated with the use of only pentazocine for post caesarean section analgesia (p-value=0.009). There was no difference on the level of satisfaction between the participants on pentazocine only and those on combined pentazocine and diclofenac (p-value ≥0.05).

The combined use of pentazocine and diclofenac for 24 hour post caesarean section analgesia achieving better pain relief than the use of only pentazocine in this study is similar to the previous findings

in Osogbo and Ife, southwest Nigeria, Kano, northern Nigeria, Iran and Switzerland [25-29]. Despite the differences either in the drug dosages or types of analgesics used in these studies, their findings showed that multimodal post caesarean section analgesia achieve a better pain relief than unimodal analgesia. The improved analgesia obtained with the combination of the pentazocine and diclofenac could be explained by the effect of combined action of two different analgesics that interrupt pain transmission at different levels resulting in additive or synergistic analgesia.

Though the level of satisfaction from the combined pentazocine and diclofenac analgesia and the pentazocine only analgesia were 87.1% and 77.1% respectively, there was no statistical significant difference between them. This is contrary to the findings by Olateju SO et al., in Ife and Adamou N et al., in Kano, where patients with multimodal analgesia were significantly more satisfied than the ones on unimodal analgesia [26,27]. The reason for no statistical significant difference between the two groups of participants on the level of satisfaction in this study may be because Igbo women cope satisfactorily with pain [30], and they constituted 97% of the parturients that participated in this study.

Though age, parity and educational status influence pain perception among obstetric women [30,31], these variables are similar in both groups of women in this study thereby removing any confounding influence of these variables. The faster onset of postoperative ambulation, bowel sound auscultation and onset of oral feeding on patients with multimodal analgesia when compared with those on unimodal analgesia in this study is similar to the findings by Adamou et al., in Kano [27]. This is clinically important as early ambulation and initiation of oral feeding in post caesarean section patients will improve their psychological and emotional well-being. It will also encourage breastfeeding, mother to child bonding as well as prevention of thrombo-embolism, uterine sub-involution and post-partum haemorrhage. Similar to the finding in Kano [27], the analgesic mode (unimodal versus multimodal) did not have any significant effect on the duration of hospitalization. This is because not only analgesia but other factors influence the decision on the discharge of patients. Such factors comprise the surgeon's preference, choice and use of antibiotics, degree of wound healing, type of anterior abdominal wall incision (midline versus pfannenstiel incision) and maternal and neonatal clinical conditions. With the exception of maternal drowsiness experienced more by the patients on only pentazocine, the side effect profile was essentially similar in both groups. The reduced side effect profile in the pentazocine-diclofenac group compared to pentazocine only group may be because the cumulative effect of both drugs tends to reduce the side effects. Despite the advantages of multimodal analgesia over unimodal analgesia identified in this study, the high cost of combined use of pentazocine and diclofenac for post caesarean section analgesia in this study may prevent the patients from using it. This underscores the need for free obstetric services in this environment.

LIMITATION

This study is weakened by pain being a subjective experience and therefore, the authors may not have been able to measure with certainty, how much pain each parturient felt. This was a single centre study which may not conclusively reflect the findings in other hospitals and therefore a multi-centre study is required.

CONCLUSION

The combined use of pentazocine and diclofenac in post caesarean section analgesia is more effective in achieving a satisfactory pain relief and has less side effects when compared with pentazocine only. This is very important especially in a resource-poor country like Nigeria where potent opioids are not readily available and affordable and yet there is need to achieve optimum pain control following caesarean section.

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