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ORIGINAL ARTICLE

ORAL PARACETAMOL VERSUS ORAL DICLOFENAC IN THE CONTROL OF UTERINE CRAMPING PAIN AFTER VAGINAL BIRTH

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ABSTRACT

Introduction: *Uterine cramping pain is a documented morbidity in the immediate postpartum period but there is no protocol for its management. The study aims to compare the effectiveness of multiple doses of oral paracetamol and diclofenac in the control of uterine cramping pain in women that had spontaneous vaginal delivery*
Methods: *It is a randomized controlled study among 291 women that had spontaneous vaginal delivery at LAUTECH Teaching Hospital Ogbomoso. They were recruited in the labour ward and randomized into Paracetamol, Diclofenac or Placebo groups. Initial pain intensity was assessed followed by administration of the drugs within 1hour of delivery and then 8 hourly until 24 hours. The instrument of survey was a proforma, and data were analyzed using SPSS 22. Primary outcomes were adequacy of pain relief, onset of breastfeeding and maternal satisfaction. Secondary outcome was potential maternal side effects of the drugs.*
Results: *The incidence of after-pain was found to be 100% with a large proportion (97.9%) being severe. Respondents' age, gestational age, duration of labour and oxytocin augmentation of labour correlated significantly with severity of pain. Diclofenac was significantly better than paracetamol which in turn was better than placebo in relieving the pain, mean SPID- 8.71 (SD-1.17; CI-8.48-8.95), 6.78 (SD-2.25; CI-6.33-7.24) and 1.54(SD-1.35, CI-1.26-1.31), F-487.31; p< 0.001 for diclofenac, paracetamol and placebo, respectively. Side effects were seen only in diclofenac group.*
Conclusion: *Multiple doses of oral Diclofenac and Paracetamol were effective in relieving uterine cramping after-pain although pain relief was more with diclofenac.*
Key words: *uterine cramp, after-pain, postpartum analgesia, Diclofenac and Paracetamol*

INTRODUCTION

Child birth is known to be a pain-associated event which gives considerable physical and psychological distress to the parturient and her care giver and if improperly managed could jeopardise the woman's reproductive career. (1-3) Apart from the pain experienced during labour and delivery, new mothers may experience pain following child birth from incision of caesarean delivery, perineal lacerations including episiotomy, the nipple while breastfeeding and uterine contractions associated with uterine involution. (3,4) Shift of attention from the mother to her newborn makes the management of after birth pains to be less researched unlike the management of labour pains. (5, 6)

A significant event of the puerperium is uterine involution which is the physiological process by which the uterus returns to the pre-pregnancy state after delivery through cytoplasmic autolysis aided by uterine contraction. (6, 7) This uterine contraction is what is perceived as uterine cramping after pain and has been found to be more in multipara than primipara. (2,7,8) Although this pain is subjective and can be confusing to new mothers, it has invariably been described as being similar to menstrual pain, felt in the lower abdomen and back with severity likened to that of labour pain. (7,8) This pain has been described as being severe enough to require the most potent analgesia.(7-9,10,11)

The justification for this study is based on the fact that uterine cramping pain can impair successful breastfeeding, the mother's ability to care for her newborn and the establishment of good-quality mother-baby interaction. (11-13) it can also result in maternal neuro-hormonal stress responses, sleep and emotional disorders, anxiety, depression and mother's inability to perform her daily routine. (3,12,14,15) Hence, the goals of safe motherhood cannot be achieved without effective management of after-pain from uterine cramps. (16,17)

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The study aimed to determine the incidence, pattern and determinants of after pain and to compare the efficacy of multiple doses of oral paracetamol 1000mg, diclofenac potassium 50mg and that of placebo in relieving it.

MATERIALS AND METHODS

It was a randomized controlled study among consenting women that had spontaneous vaginal delivery in the labour ward of LAUTECH Teaching Hospital Ogbomoso, South-Western Nigeria. Exclusion criteria were women that had postpartum haemorrhage, women on drugs with known or possible analgesic or anxiolytic effects including women who had epidural analgesia in labour, women with history of peptic ulcer disease or bleeding disorders, significant renal or liver impairment, preeclampsia, asthma, women with intrauterine fetal death or stillbirth and women on anticoagulants.

Approval was obtained from the ethical committee of the hospital with protocol number LTH/OGB/EC/2016/118. Consenting participants were randomized into intervention (diclofenac or paracetamol) or control (placebo) groups using simple random sampling. The interventional group was either diclofenac potassium tablets (Cataflam® by Novartis pharmaceuticals) administered at the dose of 50mg 8hourly or paracetamol tablets (Easadol® by May & Baker pharmaceuticals) administered at the dose of 1000mg 8hourly. The control group had placebo administered in two tablets 8 hourly.

Sample size for the study was 291 (n=97 in each group) calculated using formula for multiple arm randomized control trial for continuous variable.(18) The social class of the patients was determined by the patient's level of education and her husband's occupation using Olusanya and co-workers classification system. (19)

The mean Summed Pain Intensity Difference employed was obtained from a pilot study assuming effect size of 0.54, power of 90% at 95% confidence level and attrition rate of 10%. Women attending antenatal clinic were informed about the study but recruitment was done when they presented in labour. The management of labour, delivery and postpartum period was done according to the departmental protocol. This included active management of labour, partho-graphic monitoring of labour and administration of intramuscular pethidine 100mg 4hourly until cervical dilatation was 6cm.

Immediately after vaginal delivery, (within 1 hour of initiating breastfeeding or within 1hour post-delivery, for parturients that could not breastfeed), all the women that met the inclusion criteria were counselled and written consent was obtained followed by baseline pain evaluation and then randomisation into the study groups. The chosen drug was then administered. Thus Easadol® 1000mg or Cataflam® 50mg or Placebo was administered orally, after food, to the assigned group. Subsequently, at 8th, 16th and 24thhour or at discharge, whichever came first, administration of drug was repeated and other aspects of the proforma were appropriately administered. The study was discontinued in any respondent who developed known side effects associated with any of the drugs. Any participant that expressed uncontrolled pain in between the stipulated hours of drug administration was given tramadol tablet 50mg, per oris, statim for the break through pain.

The baseline pain intensity within 1 hour post-delivery and at each of 8th, 16th and 24th hour was assessed using 11-point numeric pain intensity scale with zero indicating no pain and 10 the worst pain. For the extent of pain relief, the difference between two consecutive pain intensity measurements was calculated. The resultant pain intensity difference at each time was summed to give one numerical value, the Summed Pain Intensity Difference (SPID), for each subject. The higher the SPID the greater is the pain relief. Maternal satisfaction about pain relief was also assessed using Pain Relief Satisfaction Scale.

Primary outcomes were adequacy of pain relief, onset of breastfeeding and maternal satisfaction. Secondary outcome was potential side effects of the study drugs.

IBM SPSS version 22(20) was used for data entry and analysis. To determine significance, chi square test was used for categorical variables while ANOVA test was used when comparing difference in more than two means. Post Hoc test was performed to confirm any difference that occurred between two groups whenever ANOVA test showed overall statistical difference in the group means. Correlation analysis (Spearman rho and Pearson) were used to test relationships. Logistic regression analysis was also performed to check the effect of the need for additional analgesia among the groups. Level of significance was set at p value ≤ 0.05.

RESULTS

The study was carried out between 25th July 2017 and 12th May 2018. Table 1 depicts the baseline profile of the participants.

The participants were evenly distributed across the study groups as the observed difference in the distribution was not statistically significant.

Table 1: Characteristics of participants

Variables	Study Group			Total N(%)	Test statistics	p-value
	Diclofenac n(%)	Paracetamol n (%)	Placebo n(%)			
Age (in years)					**χ^2=7.859**	0.447
<25	20 (34.5)	19 (32.8)	19 (32.8)	58(100)		
25 – 29	23 (34.8)	20 (30.3)	23 (34.8)	66(100)		
30 – 34	23 (27.1)	32 (37.6)	30 (35.8)	85(100)		
35 – 39	24 (43.6)	13 (23.6)	18 (32.7)	55(100)		
40 and above	7 (25.9)	13 (48.1)	7 (25.9)	27(100)		
Total	97	97	97	291		
Mean Age ±SD	30.43±6.4	30.92±6.6	30.20±6.4	30.51±6.4	**F= 0.322**	0.725
Religion					**χ^2= 7.293**	0.065
Christians	52 (28.7)	62 (34.3)	67 (37.0)	181(100)		
Muslims	45 (41.3)	35 (32.1)	29 (26.6)	109(100)		
Others	0 (0.0)	0 (0.0)	1 (100.0)	1(100)		
Total	97	97	97	291		
Ethnicity					**χ^2=4.259**	0.802
Hausa	4 (26.7)	5 (33.3)	6 (40.0)	15(100)		
Igbo	10 (41.7)	8 (33.3)	6 (25.0)	24(100)		
Yoruba	74(31.9)	78(33.6)	80 (34.5)	232(100)		
Others	9 (42.1)	6 (31.6)	5(26.3)	20(100)		
Total	97	97	97	291		
Marital Status					**χ^2= 1.373**	0.616
Single	5 (50.0)	2 (20.0)	3 (30.0)	10(100)		
Married	92 (32.7)	95 (33.8)	94 (33.5)	281(100)		
Total	97	97	97	291		
Socio-economic class						
High	0 (0)	0 (0)	0 (0)	0(0)		
Middle	97 (33.3)	97 (33.3)	97 (33.3)	291(100)		
Low	0 (0)	0 (0)	0 (0)	0(0)		
Total	97	97	97	291		
Parity					**χ^2= 4.626**	0.328
Primiparous	23 (41.8)	15 (27.3)	17 (30.9)	55(100)		
Multiparous	66 (30.7)	73 (34.0)	76 (35.3)	215(100)		
Grand multiparous	8 (38.1)	9 (42.9)	4 (19.0)	21(100)		
Total	97	97	97	291		
Gestation age at delivery					**χ^2=3.141**	0.222
Preterm	9 (50)	6 (33.3)	3 (16.7)	18(100)		
Term	88 (32.2)	91 (33.3)	94 (34.4)	273(100)		
Total	97	97	97	291		
Types of Gestation					**χ^2=3.655**	0.169
Single	94 (33.5)	91 (32.4)	96 (34.2)	281(100)		
Multiple	3 (30.0)	6 (60.0)	1 (10.0)	10(100)		
Total	97	97	97	291		
Duration of Labour					**χ^2=24.08**	**<0.001**
≤8hours	22 (73.3)	4 (13.3)	4 (13.3)	30(100)		
>8hours	75 (28.7)	93 (35.6)	93 (35.6)	261(100)		
Total	97	97	97	291		
Augumentation of Labour	38 (45.8)	22 (26.5)	23 (27.7)	83(100)	**χ^2=8.125**	**0.020**
Yes	59 (28.4)	75 (36.1)	74 (35.6)	208(100)		
No	97	97	97	291		
Total						
Commenced Breastfeeding within 1 hour of delivery	86 (31.9)	92 (34.1)	92 (34.1)	270(100)	**χ^2=3.695**	0.207
Yes	11 (52.4)	5 (23.8)	5 (23.8)	21(100)		
No	97	97	97	291		
Total	11 (52.4)	5 (23.8)	5 (23.8)	21(100)		
Reason for not commencing BF	8.77± 1.19	8.91± 1.00	8.78± 0.97	8.82±1.06	**F 0.480**	0.619
Baby is in SCBU						
Baseline Pain Intensity						
Mean ±SD						

A total of 291 women who gave informed consent were enrolled for the study and randomised equally into intervention groups; diclofenac (n – 97), placebo (n – 97) and control (placebo) group (n – 97).

Table 2: Incidence and pattern of after pain intensity among the study participants

Pain Intensity	Frequency	Percentage
No pain	0	0.0
Mild pain	0	0.0
Moderate pain	6	2.1
Severe pain	285	97.9

All participants completed the study and were analysed.

Table 2 shows the incidence and pattern of uterine cramping after pain among the participants. The incidence of uterine cramping after pain was 100%.

No respondent reported no or mild pain intensity. Most (97.9%) of the respondents reported severe pain while only 2.1% reported moderate pain intensity.

Table 3: Factors affecting severity of pain among the respondents

Factors	Pain Severity				Total	χ^2	p-values
	Moderate		Severe				
	n	(%)	n	%			
Marital Status							
Married	5	1.8	276	98.2	281(100)		
Single	1	10.0	9	90.0	10(100)	3.232	0.072
Number of gestation							
Single	6	2.1	275	97.9	281(100)		
Multiple	0	0.0	10	100.0	10(100)	0.218	0.641
Augumentation							
Yes	4	4.8	79	95.2	83(100)		
No	2	1.0	206	99.0	208(100)	4.372	0.037
Religion							
Islam	2	1.8	107	98.2	109(100)		
Christianity	4	2.2	177	97.8	181(100)	0.069	0.966
Others	0	0	1	100	1(100)		
	Pain intensity						
			Pearson Correlation Coefficient (r)				p-value
Age			0.225				<0.001
Parity			0.083				0.158
Gestational age			0.177				0.002
Duration of labour (in minutes)			0.190				0.001

Table 3 shows the relationship between the respondents' socio-demographic profile and severity of pain. Oxytocin augmentation of labour, respondents' age, gestational age and duration of labour were positively correlated with the pain intensity.

Table 4: Efficacy of Analgesic on After Pain Relief: using SPID, maternal satisfaction, need for additional analgesia and maternal side effects

		Mean	SD	95% Confidence Interval for Mean Lower Bound	Upper Bound	Min	Max	F	p-value
Maternal satisfaction	Diclofenac	9.51	1.12	9.28	9.73	2.00	10.00	515.18	<0.001
	Paracetamol	6.87	2.46	6.37	7.36	.00	10.00		
	Placebo	1.60	1.35	1.33	1.87	.00	8.00		
	Total	5.99	3.72	5.56	6.42	.00	10.00		
Summed Pain Intensity Difference	Diclofenac	8.71	1.17	8.48	8.95	6.00	10.00	487.32	<0.001
	Paracetamol	6.78	2.25	6.33	7.24	.00	10.00		
	Placebo	1.54	1.35	1.26	1.81	.00	8.00		
	Total	5.68	3.46	5.28	6.08	.00	10.00		

Need for additional analgesia/maternal side effects

Variables	Study Group Diclofenac n (%)	Paracetamol n (%)	Placebo n (%)	Test statistics	p value
Need for additional analgesia					
Yes	3 (2.8)	19 (17.9)	84 (78.2)	X2= 163.86	<0.00
No	94 (50.8)	78 (42.2)	13 (7.0)		1
Total	97	97	97		
Reason for additional analgesia					
Abdominal pain	1 (100)	0 (0.0)	0 (0.0)	X2= 204.18	<0.00
Uterine Contraction pain	2 (1.92)	16 (15.38)	86 (82.70)		1
Side effect*					
Dyspepsia	2 (100)	0 (0.0)	0 (0.0)	X2=2.65	0.331
Epigastric pain	6 (100)	0 (0.0)	0 (0.0)	X2=9.47	0.004
Others					

Post Hoc test of Maternal Satisfaction and SPID

Dependent Variable	(I) identification	(J) identification	Mean Difference (I-J)	Sig.	95% Confidence Interval Lower Bound	Upper Bound
Maternal satisfaction	Diclofenac	Paracetamol	2.63918*	<0.001	2.0482	3.2301
		Placebo	7.90722*	<0.001	7.3163	8.4982
	Paracetamol	Diclofenac	-2.63918*	<0.001	-3.2301	-2.0482
		Placebo	5.26804*	<0.001	4.6771	5.8590
	Placebo	Diclofenac	-7.90722*	<0.001	-8.4982	-7.3163
		Paracetamol	-5.26804*	<0.001	-5.8590	-4.6771
Summed Pain Intensity Difference	Diclofenac	Paracetamol	1.92784*	<0.001	1.3674	2.4883
		Placebo	7.17526*	<0.001	6.6148	7.7357
	Paracetamol	Diclofenac	-1.92784*	<0.001	-2.4883	-1.3674
		Placebo	5.24742*	<0.001	4.6870	5.8079
	Placebo	Diclofenac	-7.17526*	<0.001	-7.7357	-6.6148
		Paracetamol	-5.24742*	<0.001	-5.8079	-4.6870

Table 4, the mean SPID was most in diclofenac group: 8.71 [SD-1.17; 95% CI- 8.48-8.95] and least in placebo group: 1.54 [SD-1.35; CI-1.26-1.81].

The test of association was significant (F-487.31; p-<0.001) in all the groups.

DISCUSSION

The participants were evenly distributed across the study groups. The mean age of the respondents was 30.6 ± 6.5years which is similar to the mean age (30.4 ± 4.8years) of the women in Imarengiaye and co-workers' study. (10) This could be due to similar geographical location, Nigeria. However, this mean age is higher than the mean age (27.9 ± 4.2 years) obtained by Mahin and co –workers in Iran.21 This could be due to lower age of marriage among Arab women. (21) Yoruba ethnic group constituted majority (80%) of the study population, this is because of the geographical location of the study setting, Ogbomoso south-western Nigeria, which is a Yoruba land. Although all the women in this study belonged to the middle socioeconomic class, majority of them (57%) had tertiary level of education, 30% of them had secondary level of education and only 13% of them had primary level or no formal education. This is similar to the finding of Olayemi and co-workers which showed that the Yoruba ethnic group has high educational status. (22)

The incidence of uterine cramping after-pain was 100%, similar to the finding of Holdcroft and co-workers in which 96% of the respondents reported after - pain. (11) Also, Imarengiaye and co-workers found a large percentage (82.8%) of their respondents reporting after-pain. (10) In the present study, the mean baseline pain intensity was 8.82 [SD- 1.06; 95% CI-8.69-8.94; F -0.480; p-0.619] which is similar to the baseline pain intensity obtained in the pilot study, 8.24. This could be due to similar geographical region and hence, similar population study. In this study, a larger proportion (97.9%) reported severe pain, while only 2.1% reported mild pain, and no respondent reported mild or no pain. This could be because majority of the study population were of high educational status in similarity to the finding of other studies in which high educational status was shown to correlate positively with increased westernization and hence increased perception and desire for pain relief.(22,23) This is also similar to Thompson and co-workers' finding of larger proportion (52.1%) of their respondents reporting severe pain. (24) However, Declercq and co-workers found more respondents (50-80%) reporting moderate pain and less (10-18%) reporting severe pain; this could be due to difference in the study population as the participants were mostly of low parity and the study was limited to women who gave birth to single baby and could participate in English. (25)

In this study, correlation analysis shows that increasing parity correlated positively with pain intensity which agrees to the findings of Holdcroft and Eshkevari, Declerq and co-workers in which parity correlated positively with severity of pain intensity. (11,25,26)

Moreover, respondents' age, gestational age, duration of labour and oxytocin augmentation of labour were found to correlate significantly with severity of pain intensity. This is similar to previous documentations in literature that longer duration of labour and delivery cause more stress and fatigue for mothers and this correlated positively with need for additional narcotics after delivery. (11-13)

However, Taffazoli and co-workers found no significant association between socioeconomic factor, oxytocin augmentation, duration of labour and severity of after-pain. This could be due to difference in sampling method and study population. (21) Taffazoli and co-workers used convenience sampling and the study group was composed, mainly, of younger age group and housewives. Also, breastfeeding was an exclusion criterion. In this study, test of significance could not be applied to socioeconomic class as all the respondents were of middle class; this could be due to the study setting (tertiary health facility).

In this study, analysis of post intervention pain intensity, using ANOVA, showed significance in the three groups at each of 8^{th}, 16^{th} and 24^{th} hour post-delivery ($p = 0.000$). Post Hoc analysis of these variables revealed that placebo and paracetamol groups were responsible for the difference in pain intensities. Placebo group had higher pain intensity than paracetamol group, the pain intensity of which in turn was more than that of diclofenac group. This is similar to the finding of Skovlund and co-workers, (27) in which placebo group had higher pain intensity compared to paracetamol group at 2 hour post intervention. Moreover, ANOVA showed statistical significance in pain relief evaluation among the three study groups. The Post Hoc analysis revealed that the significance was in the diclofenac and paracetamol group ($p<0.001$). Diclofenac was significantly better than paracetamol which in turn was better than placebo in relieving uterine cramping after-pain. This is similar to the conclusion in the study by Huang *et al* and the Cochrane review which stated that NSAIDS were significantly better than placebo in the control of uterine cramping after pain.(28,29) It is also similar to Skovlund and co-workers' finding of oral paracetamol 1000mg being significantly better than placebo in the control of uterine involution pain. (27)

Majority (92.7%) of the respondents in this study commenced breastfeeding within one hour of delivery, while only 7.3% did not.

The reason reported for not commencing breastfeeding was that baby was admitted into the special care baby unit. Uterine cramping after pain was not associated with breastfeeding in this study, unlike the finding in a survey of childbearing experiences in USA in which 71% of the women reported difficulty in breastfeeding mainly due to uterine cramping pain. This could be because the latter study was an observational study which enabled unmodified assessment of the effect of breastfeeding on uterine cramping after-pain.(17)

Side effects were significantly higher in diclofenac when compared to the paracetamol and placebo groups but similar in paracetamol and placebo groups. The side effect was mainly epigastric pain which was ameliorated with the administration of antacid. None of the respondents with side effects expressed concern to necessitate the need to discontinue the study on account of the side effects.

This is in keeping with the conclusion of the Cochrane review in which paracetamol 1000mg had similar maternal side effects as placebo. (29)

Conclusion

Multiple doses of either oral Diclofenac or oral Paracetamol were effective in significantly relieving uterine cramping after-pain, although more with diclofenac at the risk of more maternal side effect compared to paracetamol or placebo.

Conflict of interest: All authors declare that they have no competing interests.

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