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Intravenous Paracetamol versus Intramuscular Tramadol in Shortening the Duration of Labour: A Randomized Controlled Trial

Uzoma Ogbonna-Onwukwe[1], Assumpta Nnenna Nweke[1*], Arinze Ikeotuonye[2], Chukwudi Olugu Oru[1], Chinwe Wendy Oliobi[1], Ifeoma Cecilia Uche-Omovoh[1], Chinedu John Obasi[1], Ugochukwu Raphael Chikezie[1], Chinyere Chibuzo Duru[1]

[1]Department of Obstetrics and Gynaecology, Alex Ekwueme Federal University Teaching Hospital, Abakaliki, Ebonyi State
[2]Department of Obstetrics and Gynaecology, Nnamdi Azikiwe University Teaching Hospital, Nnewi, Anambra State, Nigeria
Email: *ninasophia4iyke@gmail.com

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Abstract

Background: The excruciating pain associated with labour has led to different studies aimed at finding pharmacolologic and non pharmacologic ways of shortening the duration of labour. Most agents used are either expensive or associated with fetomaternal adverse effects. This has led to the study of paracetamol and tramadol that have analgesic properties and have shown to have effect on labour duration. **Aim**: To compare intravenous paracetamol versus intramuscular tramadol in shortening the duration of labour at Alex Ekwueme Federal University Teaching Hospital and St Patrick's Mile 4 Hospital, Abakaliki, Ebonyi State. **Methodology:** It is an open label, non-inferiority randomized controlled trial that was conducted on one hundred and eighty-nine parturients in active labour. Group A received 1000 mg of intravenous paracetamol while Group B received 100 mg of intramuscular tramadol and allocation was in the ratio of 1:1. Labour duration in the active phase was noted. Data were analyzed using SPSS version 25. **Results**: The mean labour duration in the paracetamol and tramadol groups were 176.3 ± 105.7 and 215.9 ± 120.8, $P < 0.018$. This finding was statistically significant. Also, the total duration of labour was statistically significant between groups with mean labour duration in paracetamol and tramadol groups 206.3 ± 121.09 248.6 ± 138.61 respectively, $p < 0.018$ There were no significant differences in the other stages of labour, fetomaternal side effects and maternal satisfaction. **Conclusion:** This study showed that 1000 mg intravenous paracetamol was not inferior to 100 mg intramuscular tramadol in shortening the duration of labour.

Keywords

Labour Duration, Intravenous Paracetamol, Intramuscular Tramadol

1. Introduction

Labour pain is described as excruciating but yet desirable because of the birth of a child associated with the process [1]. labour pain is categorized high on the pain rating scale when compared to other kinds of pain from many conditions [2]. Labour pain is part of a normal physiological process and can been managed effectively by skilled birth attendant for a good outcome [2] [3]. As a result of the excruciating pain associated with labour, so many women are worried about it (especially when the labour is prolonged) and how they can either relieve the pain or shorten the duration of labour [4] [5].

Oxytocin is a hormone produced in the supraoptic and paraventricular nuclei of the hypothalamus and released into the circulation from the posterior pituitary lobe [6]. The synthetic oxytocin has been used to augment and shorten the duration of labour, however, it has been found to cause uterine rupture and foetal hypoxia [6] [7]. Misoprostol a prostaglandin E1 analogue has been used to shorten the duration of labour with huge successes. However, it's been found to cause uterine hyperstimulation, fetal tachycardia and increased rate of caesarean section [8]. Other agents that have been used to shorten the duration of labour include drotaverine hydrochloride but is relatively scarce and more expensive than most agents needed to reduce labour duration [9]. Hyoscine butylbromide has been shown by a systematic review to be effective in the reduction of labour more in primigravidas than multiparas, however has been shown to have anticholinergic effect and no analgesic effects [10]. Valethamate bromide was shown to shorten the second stage of labour in nulliparous women with some anticholinergic side effects [11]. Tramadol hydrochloride in its parenteral form (intramuscular) is commonly used in labor analgesia in developing countries like ours. It is cheap; requires no special monitoring and has been widely studied and proven for its safety and efficacy in labor analgesia but has not been shown to reduce the duration of labour [12].

Tramadol, a centrally acting analgesic with a multiple mechanisms of action [13] has been shown to be effective and well tolerated with the main adverse reactions being nausea, dizziness and vomiting particularly at start of therapy [14]. Vellanki *et al.* [15] in their study showed that tramadol was an effective and safe analgesia and also shortened the duration of labour. Also, Vanitha *et al.* [16] found that tramadol relieved pain and shortened the duration of labour in primigravida.

Paracetamol, a CNS cyclooxygenase inhibitor, is a first line treatment for acute pain [17] [18]. This agent has been found to shorten the duration of labour in the study conducted by Gholami *et al.* in nulliparous women [17]. It is cheap, devoid of the anticholinergic side effects experienced with the use of other agents and is relatively safe [18]. Although it is readily available, it is rarely used in the management

of labour. There is paucity of data in Nigeria showing the efficacy of IV paracetamol in the shortening of labour necessitating this study to compare the efficacy of intravenous paracetamol and intramuscular tramadol in shortening labour duration.

2. Material and Methods

2.1. Study Background

The study was done at AEFUTHA and St. Patrick's Mile 4 Hospital Abakaliki, Ebonyi state. Ebonyi state is one of the 5 south eastern states in Nigeria. The state has a population of about 3 million people and occupies a land mass of 5932 kilometers square. Majority of the inhabitants engage in subsistent farming, petty trading and civil service as their occupation. Literacy level generally is low while poverty is prevalent among this population.

AE-FUTHA was established in December 2011. It receives referrals from all parts of the state and neighboring states of Abia, Benue, Cross-River and Enugu. There are 54 obstetric bed spaces including postnatal and antenatal wards. Preliminary data showed that the hospital had 984 deliveries in 2021 with approximately 82 deliveries per month.

St. Patrick's Mile 4 Hospital, Abakaliki was established in 1948. It is a missionary hospital managed by Reverend Sisters. They also manage antenatal cases, labour and delivery.

2.2. Study Population

These were booked women in active phase of labour at AEFUTHA and St Patrick Mile 4 Hospital, Abakaliki.

2.3. Study Design

This was an open label randomized controlled trial.

2.4. Inclusion Criteria

Inclusion criteria involved pregnant women carrying live singleton fetuses in cephalic presentation who had spontaneous onset of labour at term with the labour in active phase.

2.5. Exclusion Criteria

Pregnant women excluded from the study included: Women with clinical evidence of cephalopelvic disproportion, malpresentation, multiple pregnancy, previously scarred uterus, preterm labour, induced labour and antepartum hemorrhage. History of known allergy to tramadol and paracetamol or opioids or history of narcotics dependency. Also, history of renal disease, fetal distress and intrauterine fetal death.

2.6. Sample Size Determination

Sample size formula for an inferiority RCT by Zhong [19].

$N = 2\ (z_{1-\alpha} + z_{1-\beta})^2 S^2/\delta_0^2$. N = 78.5, 20% attrition 95 per arm

2.7. Ethical Approval

The ethical approval for the study was obtained from the Health Research Ethics Committee of Alex Ekwueme Federal University Teaching Hospital, Abakaliki, Ebonyi State, Nigeria with ethical approval number: AEFUTHA/REC/VOL 3/2022/130 and Registration No-RE/M4H/86/22 respectively.

2.8. Patients' Selection Method

Following counselling of women each day at the antenatal clinic, history and physical examination was conducted to ascertain eligibility. Women who met the inclusion criteria and gave consent were selected for the study through simple random sampling—A pool of pieces of paper written "Yes" and "No" (in equal proportion) and folded was placed in a container, from which the women picked. Those who picked "Yes" were selected for the study while those who picked "No" were not. Those selected for the study were further counselled on the details of the study and randomized into two groups as detailed below.

2.9. Randomization and Allocation

The participants were randomized by means of a computer-generated list of random numbers using the software Research Randomizer. Using this software, a set of ninety seven numbers were randomly generated from a pool of one hundred and ninety four numbers (1 - 190) and assigned to Group A (intravenous paracetamol group) while the remaining set of ninety seven numbers were automatically assigned to Group B (intramuscular tramadol group). These numbers (1 - 190) were inscribed on pieces of paper with the corresponding drug name "paracetamol or tramadol". These pieces of paper were then inserted into brown envelopes which have been correspondingly numbered according to the number on each piece of paper. They were then arranged sequentially (from 1 to 190). All the envelopes were kept in a locker that was made accessible to all the members of the research team. Participants who met the inclusion criteria and have signed the informed consent form were given sequential study numbers and the corresponding numbered opaque sealed envelope was then allocated to the patient. The particular drug contained in the numbered envelope, corresponding to the patient's study number was given to the patient.

2.10. Study Procedure

All the enrolled women had a proforma which was filled at the time of admission into the labour ward. Antenatal records of the patients were reviewed, history obtained and physical examination was done, and then those who gave informed consent on admission and meet the inclusion criteria were randomized into the study. Each patient was further educated about the trial drugs. Group A received a 100 ml intravenous infusion containing 1000 mg paracetamol single dose over 15 min. Group B received intramuscular tramadol hydrochloride 100 mg single

dose at the upper and outer quadrant of gluteal region with a 2 ml syringe. Intrapartum monitoring was done with the individualized partograph and all patients had amniotomy as appropriate following allocation. The duration of the first, second, third and total duration of labour between the two groups were documented as well as side effects of the drugs, neonatal outcome and maternal satisfaction following the administration of the drugs.

The patients were made to know that their involvement was voluntary and that they could withdraw from participating at any point during the study. They were also made to understand that if they withdrew from the study, their decision would not affect their subsequent care from the labour ward staff.

2.11. Quality Control

Quality control was maintained by ensuring that the drugs were of the same brand, batch number and had not expired. They were also stored in an air conditioned room.

2.12. Outcome Measures

Primary Outcome Measure -this was the mean duration of active first, second third stages of labour.

Secondary Outcome Measures-The secondary outcome measure included: total duration of labour, maternal and fetal side effects, participants' satisfaction following delivery.

2.13. Operational Definitions

Active Phase of labour—This is the duration of labour from 4 centimeters cervical dilatation to 10 centimeters (full) cervical dilatation.

Second stage of labour—This is from full cervical dilatation to the delivery of the baby.

Third stage of labour—This is from the delivery of the baby to the delivery of the placenta.

2.14. Statistical Analysis

Data was collated, tabulated and then statistically analyzed using IBM SPSS version 25, Chicago II, USA. Chi-square test (or Fisher's exact test where applicable) was used for comparison between groups for categorical variables while student t test was used for comparison of means between groups for continuous variables. A difference with a P value < 0.05 was considered statistically significant.

3. Result

One hundred and ninety participants were recruited for the study but one participant declined in the tramadol group. Table 1 shows the socio-demographic/obstetric characteristics of participants with no significant difference in any of the parameters between the two groups. Table 2 shows the duration of labour among

the two study groups. At the first stage, the mean duration of labour was longer in Group B with Tramadol (215.9 ± 120.8 minutes) when compared with Group A with Paracetamol (176.3 ± 105.7 minutes). The difference in the mean was statistically significant (p = 0.018). At the second stage, Group B had a longer mean duration of labour (24.7 ± 16.4 minutes) compared with Group A (23.0 ± 13.2 minutes), although, the difference in the means was not statistically significant (0.420). In total, the mean duration of labour was higher in Group B (248.6 ± 138.61 minutes) than in Group A (206.3 ± 121.09 minutes). The difference in their means was statistically significant (p = 0.018). Table 3 shows the maternal side effects of the trial drugs. A total of 10% of the participants in Group B had sedation compared with 1% in Group A and the difference was not statistically significant (p = 0.188). There were no statistically significant differences among the study groups for side effects of Nausea (p = 0.442) and vomitting (p = 0.766). Table 4 shows the perinatal outcomes among the two study groups. There was no statistically significant difference in the proportions of the Apgar scores of the newborns at the first minute (p = 0.6365) and at the fifth minute (p = 0.204). Table 5 shows maternal satisfaction in both study groups. A greater proportion of participants in the Paracetamol Group (9.5%) was very unsatisfied compared with those in the Tramadol Group (3.2%), but the difference was not statistically significant (p = 0.132). Comparable proportions of participants in both groups, 7.4% to 6.3% were unsatisfied with the analgesia administered and the difference was not statistically significant. A total of 22.3% of participants in the Tramadol Group were neither unsatisfied nor satisfied when compared with 18.9% in the Paracetamol Group and the difference was statistically significant. Forty six percent of participants in the Tramadol group were satisfied compared to 36.8% in the Paracetamol group. Lastly, 28.4% of participants in the Paracetamol Group compared to 18.1% in the Tramadol Group were very satisfied and the difference was statistically significant (Figure 1).

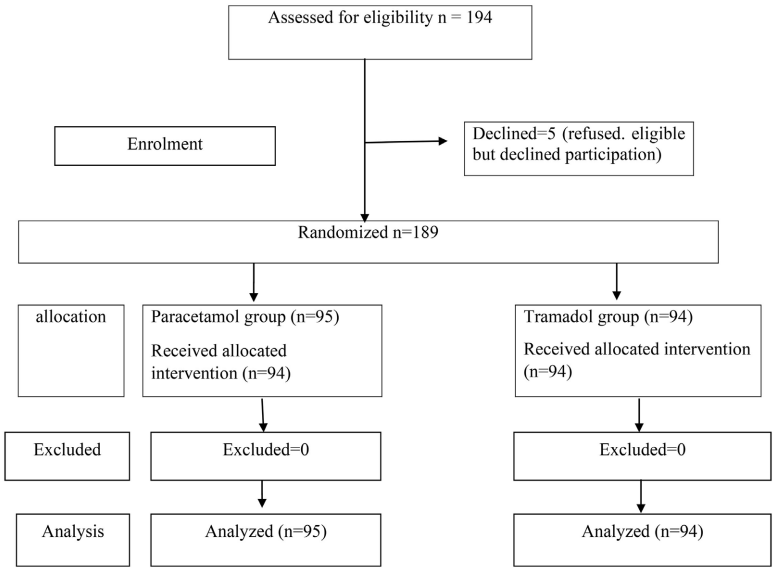

Figure 1. Consort diagram.

Table 1. Socio-demographic characteristics of respondents.

Variables	Medication Administered		χ^2/t-test	P-value
	Paracetamol (n = 95)	Tramadol (n = 94)		
Age (years)				
16 - 20	4 (4.20)	3 (3.2)	1.524	0.822
21 - 25	19 (20.0)	21 (22.3)		
26 - 30	46 (48.4)	49 (52.1)		
31 - 35	19 (20.0)	13 (13.8)		
36 - 40	7 (7.4)	8 (8.5)		
Mean ± SD	29.08 ± 4.90	28.20 ± 4.54	1.173**	0.242
Marital Status				
Single	8 (8.4)	3 (3.2)	2.357	0.125
Married	87 (91.6)	91 (96.8)		
Occupation				
Civil Servant	25 (26.3)	22 (23.4)	0.679	0.954
Trader	30 (31.6)	31 (33.0)		
Artisan	7 (7.4)	5 (5.3)		
Professional	3 (3.2)	3 (3.2)		
Unemployed	30 (31.6)	33 (35.1)		
Level of Education				
None	4 (4.3)	2 (2.1)	3.371*	0.344
Primary	31 (33.0)	28 (29.5)		
Secondary	11 (11.7)	6 (6.3)		
Tertiary	48 (51.1)	59 (62.1)		
Tribe				
Igbo	89 (94.7)	88 (92.6)	0.334	0.563
Yoruba	3 (3.2)	2 (2.1)		
Parity				
1	29 (30.5)	37 (39.4)	5.656	0.226
2	15 (15.8)	11 (11.7)		
3	23 (24.2)	20 (21.3)		
4	12 (12.6)	18 (19.1)		
≥5	16 (16.8)	8 (8.5)		
Gestational Age				
37 - 38	32 (3.7)	33 (35.1)	6.269	0.099
38.1 - 39	31 (32.6)	17 (18.1)		
39.1 - 40	23 (24.2)	34 (36.2)		
>40	9 (9.5)	10 (10.6)		

*Fisher's exact test used, **Independent sample t-test used.

Table 1 above shows the socio-demographic/obstetric characteristics of participants. This showed no significant difference in any of the parameters between the two study groups. Thus, the participants in this study were comparable in the above characteristics.

Table 2. Duration of labour among the study groups.

Stage of labour	Paracetamol (N = 95) Mean ± SD (mins)	Tramadol (N = 94) Mean ± SD (mins)	T test	P value	95% CI
First stage	176.3 ± 105.7	215.9 ± 120.8	2.393	0.018	7.04 - 72.16
Second stage	23.0 ± 13.2	24.7 ± 16.4	0.808	0.420	−2.57 - 5.97
Third stage	7.5 ± 2.19	7.9 ± 1.41	2.341	0.020	0.06 - 0.74
Total labor duration	206.3 ± 121.09	248.6 ± 138.61	2.384	0.018	7.57 - 75.83

Table 2 shows the duration of labour among the two study groups. There is a statistically significant difference between the two groups in the first and total duration of labour.

Table 3. Maternal side effects of the trial drugs.

Maternal Side Effects	Paracetamol (n = 95)	Tramadol (n = 94)	Fisher's-test	P-value
Nausea	2 (2.1)	4 (4.3)	0.711	0.442
Vomiting	5 (5.3)	6 (6.4)	0.112	0.766
Sedation	1 (1.3)	10 (10.6)	1.869	0.188
Dizziness	0 (0.0)	2 (2.1)	2.044	0.243

Table 3 shows the maternal side effects of the trial drugs with no significant difference between the two groups.

Table 4. Apgar score of neonates in the paracetamol and tramadol groups.

Neonatal Side Effects	Paracetamol (n = 95)	Tramadol (n = 94)	t-test	P-value	95% CI
1 min	7.7 ± 1.3	7.8 ± 1.2	0.554	0. 636	−0.26 - 0.46
5 min	9.6 ± 0.7	9.7 ± 0.5	1.133	0.204	−0.07 - 0.27

Table 4 shows the perinatal outcomes among the two study groups. There was no statistically significant difference in the proportions of the Apgar scores of the newborns at the first minute and at the fifth minute.

Table 5. Patient's satisfaction following labour analgesia.

Level of Satisfaction	Medication Administered		χ^2	p-value
	Tramadol (n = 94)	Paracetamol (n = 95)		
Very satisfied	17 (18.1)	27 (28.4)	7.069	0.132
Satisfied	46 (48.9)	35 (36.8)		

Continued

Neither unsatisfied nor satisfied	21 (22.3)	18 (18.9)
Unsatisfied	7 (7.4)	6 (6.3)
Very unsatisfied	3 (3.2)	9 (9.5)

Table 5 showed no significant difference in the maternal satisfaction between the two groups.

4. Discussion

The socio-demographic and obstetric characteristics of the two study groups were similar with no statistically significant difference between groups. This implies that the participants were evenly distributed between groups thereby eliminating sociodermographic characteristics as a cofounding variable.

There was a statistically significant reduction in the duration of first stage of labour in the paracetamol group when compared with the tramadol group but no significant difference in the duration of second and third stages of labour. Also, the total duration of labour was reduced in participants who received paracetamol when compared to the tramadol group and this difference was statistically significant. The difference in the duration of the first stage of labour can be deduced from the effect of tramadol as an opioid derivative causing sedation thereby leading to reduced mobility of women in labour which could lengthen the labour duration as shown in a Cochrane review by Lawrence *et al.* [19] Lawrence *et al.* noted that walking and upright positions in the first stage of labour reduced the length of labour, the risk of caesarean birth, the need for epidural, and does not seem to be associated with negative effects on mothers' and babies' well being. [19] This was similar to studies by Dwidmuthe *et al.*, [20] and Mohan *et al.* [21] in India that showed a significant decrease in duration of first stage of labour in the paracetamol group as compared to the tramadol. Studies by Lallar *et al.* [12], Bishnu *et al.* [22] and Marwah *et al.* [23] in India also observed significant reduction in the duration of 1st, 2nd and 3rd stages of labour after administration of intravenous paracetamol, hence total duration of labour was reduced in participants who received paracetamol as compared to tramadol group. Also, Rawat *et al.* found that 1000 mg of paracetamol shortened the duration of labour when compared with placebo [24]. Apgar scores of neonates at first and fifth minute were normal between the two groups and no significant difference between paracetamol and tramadol groups. This was similar to findings reported in Iran and India [2].

Sedation was the commonest side effect in the tramadol group (10.6%) followed by vomiting (6.4%) and nausea (4.3%). This finding was not statistically significant. Studies in India by Lallar *et al.* [12] also showed that there was higher proportion of women with nausea and vomiting in the tramadol group.

The study showed that out of the 189 participants, only 13 (12.7%) expressed their dissatisfaction to the drugs used in the study, out of which 7 (7.4%) were in tramadol group as and 6 (6.3%) in paracetamol group. Eighty one (85.7%) were

satisfied out of which 35 (36.8) were in paracetamol group and 46 (48.9%) were in tramadol group. Forty-four parturients were very satisfied with the drugs; 27 (28.4%) were in paracetamol group while 17 (18.1%) were in tramadol group. There was no statistically significant difference in the degree of satisfaction between the two groups (p-value = 0.132). Rehman *et al.* [25] also noted more participants in the paracetamol group were slightly more satisfied than tramadol group though this was not statistically significant. This was similar to study by Aimhaku *et al.* [26] that showed no statistical significance in maternal satisfaction among the two groups. This showed that paracetamol was equally as satisfying as commonly used tramadol in labour.

5. Conclusion

Paracetamol shortened the length of labour more and had fewer maternal adverse effects than tramadol; however neonatal outcome of both the drugs were favourable.

6. Limitations

This study was an open label study with subjectivity in patients reported outcomes. maternal side effects and maternal satisfaction may not be accurately reported with the experimental drug.

Author Contributions

UO, AI and ANN conceptualized and designed the study. COO, CWO, ICU, CJO and URC were involved in data collection/acquisition and statistical analysis; UO, ANN, AI were involved in the writing and revising the manuscript for intellectual content. All authors read and approved the final manuscript and agreed to be accountable for all aspects of the work.

Ethical Approval

The ethical approval for the study was obtained from the Health Research Ethics Committee of Alex Ekwueme Federal University Teaching Hospital, Abakaliki, Ebonyi State, Nigeria with ethical approval number: AEFUTHA/REC/VOL 3/2022/130 and Registration No-RE/M4H/86/22 respectively.

Declaration of Patient's Consent

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient (s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patient (s) understands that their names and initials will not be published and due efforts will be made to conceal their identity.

Declaration of Helsinki

The study was conducted in accordance with the ethical principles of Helsinki

Declaration.

Availability of Research Data

Authors are available and ready to supply the data upon any requests through the corresponding author.

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None.

Conflicts of Interest

There are no conflicts of interest.

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