Original Article

Pain Relief in Labor: A Randomized Controlled Trial Comparing Intramuscular Tramadol with Intramuscular Paracetamol at the University College Hospital, Ibadan, Nigeria

Aimakhu CO[1,2], Saanu OO[2], Olayemi O[1,2]

[1]Department of Obstetrics and Gynecology, College of Medicine, University of Ibadan, [2]Department of Obstetrics and Gynecology, University College Hospital, Ibadan, Nigeria

ABSTRACT

Background: Labor is considered to be one of the most painful experiences in life. Several efforts have been made over the years, particularly in the developed world, to relieve pain in labor. Unfortunately, the same attention has not been given to obstetric analgesia in most of Africa.

Aim: To compare the analgesic efficacy, patient satisfaction, and side effects of intramuscular tramadol and paracetamol as pain relief among women in labor at University College Hospital (UCH), Ibadan, Nigeria.

Materials and Methods: This was a prospective double-blind randomized controlled trial that recruited 142 parturients into two groups of 71 women. One group received intramuscular 600 mg paracetamol and the other 100 mg tramadol at recruitment with rescue dose at least 3 h apart. Maternal vital signs were monitored and labor pain was assessed using the numerical rating scale. Neonatal conditions were assessed by the use of APGAR scoring system and the need for admission into the Special Care Baby Unit. The parturients overall satisfaction with the analgesia were assessed 24 h postpartum.

Results: The sociodemographic characteristics of the pregnant women in the two groups were similar, with the mean ages being 30.89 ± 3.50 and 30.93 ± 3.82 years, respectively. The study showed that intramuscular paracetamol was as effective as intramuscular tramadol for providing moderate pain relief during active phase of labor. Neither drug caused significant changes in maternal vital signs, with favorable neonatal outcome and good safety profile.

Conclusions: This study showed that 600 mg intramuscular paracetamol provides similar and modest pain relief in labor when compared to 100 mg intramuscular tramadol. It also has fewer maternal adverse effects and favorable neonatal outcome such as tramadol. It is concluded that intramuscular paracetamol is simple, cost-effective, readily available, and feasible option as labor analgesics, especially for resource poor settings.

Key words: Labor; numerical rating scale; pain; paracetamol; tramadol.

Introduction

Labor is a painful process and may be the most painful experience many women ever encounter.[1] The experience is different for each woman, and the different methods chosen to relieve pain depend upon the techniques available locally and the personal choice of the individual patient or health workers. Pain during labor is a physiological phenomenon. The evolution of pain during first stage of labor is associated with

Address for correspondence: Dr. Christopher O. Aimakhu, Department of Obstetrics and Gynecology, University College Hospital, PMB 5116, Ibadan, Nigeria.
E-mail: chrisaimakhu@yahoo.com

Access this article online	
Website: www.tjogonline.com	Quick Response Code
DOI: 10.4103/TJOG.TJOG_17_17	

How to cite this article: Aimakhu CO, Saanu OO, Olayemi O. Pain relief in labour: A randomized controlled trial comparing intramuscular tramadol with intramuscular paracetamol at the university college hospital, Ibadan, Nigeria. Trop J Obstet Gynaecol 2017;34;XX-XX.

ischemia of the uterus during contraction as well as effacement and dilation of cervix.[2] In the second stage, pain is caused by stretching of the vagina, perineum, and compression of pelvic structures. However, pain sensation is a response of the total personality and is a subjective phenomenon.

There is no circumstance in which it is considered acceptable for a person to experience severe pain especially while under a physician's care.[3] The importance of analgesia as a contribution to overall satisfaction of pain management has been recognized increasingly in the last 50 years.[4]

Labor is generally considered to be a painful experience, and effective pain relief in labor by the use of appropriate analgesic agent is important and helpful at ameliorating the unpleasant effects of unrelieved labor pain, which include psychological disturbance, anxiety, mood depression, delayed bonding, and possible animosity to the care giver.

Epidural analgesia is the most effective analgesia for women in labor.[5] Unfortunately, epidural services are not routinely available in most obstetric units in developing countries for reasons of cost and personnel. Most labor suites, therefore, use systemic opioids for analgesia. These are cheap, simple to use, and readily available. Since its introduction in 1939, pethidine has become the most commonly used opioid for obstetric analgesia throughout the world despite unimpressive safety records,[6,7] which include nausea, vomiting, sedation, respiratory depression, and delayed gastric emptying.[5,8,9]

Tramadol is a synthetic analog of codeine that binds ∝-opiate receptors and inhibits norepinephrine and serotonine uptake.[10] Studies by Tarkilla *et al*. and Murphy *et al.* showed that tramadol is an effective analgesic without the maternal and neonatal respiratory depression common to other opioids and it does not delay gastric emptying.[11,12]

Paracetamol (acetaminophen) is one of the world's most widely used analgesics.[13] It has a central analgesic effect that is mediated through activation of the descending serotonergic pathways. Studies have shown that effectiveness of intravenous paracetamol was comparable to that of intravenous pethidine, with none of the women in the paracetamol group having adverse effects, as compared with 64% of the women receiving pethidine.[14] Another similar study comparing the effectiveness of paracetamol to pethidine in labor conducted in Iran concluded that intravenous paracetamol is more effective than intramuscular pethidine to relieve labor pain in normal vaginal delivery.[15] These two studies show the effectiveness and safety of paracetamol as labor analgesia.

Paracetamol (acetaminophen) is a safe and effective agent for pain management. Studies have suggested that paracetamol is an effective treatment for postoperative pain relief.[16,17] Studies examining analgesic effect of paracetamol in obstetrics surgeries such as abortion,[18] postoperative pain after cesarean delivery,[19,20] and perineal pain after child birth[21,22] have proposed that paracetamol has an admirable analgesic effect; however, there are limited clinical trials regarding paracetamol analgesic effect on labor pain. The available studies report similar efficacy between paracetamol and pethidine in labor without the associated feto-maternal effects of pethidine.[14,15] Studies on tramadol, an opioid analgesic, also reported less maternal sedative effect and less neonatal respiratory depression compared to pethidine.[23] Supporting this, a study by Veigas *et al.* in 1993,[24] who opined that tramadol 100 mg is as effective as pethidine 75 mg, but has a superior safety profile. The present study is, therefore, aimed at comparing the efficacy of intramuscular paracetamol with intramuscular tramadol in labor.

Materials and Methods

It was a prospective double-blind randomized controlled trial (RCT) conducted at the labor ward complex of the University College Hospital (UCH), Ibadan, Oyo State, Nigeria between the 14 April and 4 December, 2015 among the women in established labor and met the inclusion criteria. One hundred and forty-two (142) consenting pregnant women were recruited after informed consent.

This double-blind RCT compared 100 mg intramuscular tramadol and 600 mg intramuscular paracetamol in active phase of labor. Information about the trial drugs was provided to the women and they were also educated on pain assessment using numerical rating scale (NRS). The participants were made to understand that their participation was voluntary and that they had the freedom and liberty to withdraw from participating at any stage of the study and their decision would not by any way negatively or positively influence their subsequent care from the medical personnel. Consented women were recruited for the trial when in active phase of labor.

The study employed block randomization in group of 8. The sequence of randomization was generated using a computer program ensuring equal numbers of the prepared trial drugs. Due to the differences in the shape and the volume of 100 mg tramadol (2 ml) and 600 mg paracetamol (4 ml), reconstitution was done and coded by the hospital Pharmacist under aseptic conditions using sterile water to 5 ml in a syringe on a rolling basis (fresh batches were prepared as additional participants were enrolled). Both liquids were colorless, so the syringes containing the two drugs were indistinguishable.

The UCH Pharmacist, who had the randomization sequence, prepared the trial drugs into sequentially numbered envelopes in groups of 8 at a time. Each group contained four set of envelopes containing three prepared trial drugs each, to ensure that if two or more doses were given, the same drug was given both times.

The envelopes were labeled with trial numbers only known to the Pharmacist in order to conceal group allocation from the midwife, the parturients, and the researcher.

Randomization codes were placed in sequentially numbered, opaque, sealed envelope. When each woman requested for pain relief, the next numbered envelope was opened and the appropriate drug was administered by the randomizing resident or researchers. Once recruited, women were randomly allocated to receive either intramuscular paracetamol 600 mg or tramadol 100 mg slowly into the gluteus muscle or muscles of the lateral thigh.

Protocol

One hundred and seven (75.4%) participants received a single dose of the trial drugs, with 35 (24.6%) receiving two doses of trial drugs at a minimum interval of 3 h following request for rescue dose. Their pain score and maternal vital signs were assessed at intervals using NRS for the pain assessment till delivery and fetal outcome was assessed using APGAR scoring system and the need for admission to Special Care Baby Unit (SCBU).

This study aimed to use safe analgesia in active phase of labor at intervals, to alleviate or reduce labor pain to the barest minimum.

Assessment of outcome

Researchers and/or labor ward resident doctors, unaware of the type of injection given, recorded the clinical data and assessed the analgesic efficacy.

Maternal vital signs (pulse, blood pressure, respiratory rate) and labor pain were assessed immediately before giving the drug at 30, 60 min, then hourly after injection of the trial drug, till next request for analgesia or delivery.

Assessment of labor pain and pain relief was also assessed using a NRS.

The incidence of maternal vomiting, nausea, sedation, as well as any other side effects were noted. Maternal sedation was assessed on a three-point scale as: 0 = Alert, 1 = Drowsy, 2 = Asleep.

The request for rescue analgesia and the time interval after the recruitment dose was noted. Intrapartum monitoring was ensured according to our usual standard labor ward protocol. The time, duration of active phase of labor, and type of delivery were noted. Neonatal condition was assessed by the use of APGAR scoring system and the need for admission to SCBU.

The parturients overall satisfaction with the analgesia was also assessed 24 h postpartum.

Data analysis

Data obtained were coded and entered into a computer running Statistical Package for the Social Sciences, version 21 for Windows (SPSS-21). Initial analysis was done by generation of frequency tables, while further analyses were performed by cross-tabulations to explore statistical relationship between variables in the two groups. The differences between the tramadol and paracetamol groups were assessed using the nonparametric test, i.e., Chi-square test for categorical variables. The mean and standard deviation of normally distributed continuous variables were compared using the independent *t*-test. Variables not normally distributed were measured using Fisher's exact test. Numerical values were in means ± standard deviations and 95% confidence interval (CI) was calculated. Differences between the two parameters were taken as statistically significant when *P* values were <0.05.

Results

Two hundred women in labor were assessed for eligibility, out of which 160 women met the eligibility criteria for the study; however, only 142 consented and were randomized.

Sociodemographic characteristics of respondents

The sociodemographic characteristics of the women in tramadol group and paracetamol group are presented in Table 1. Patients <30 years old were 30 (42.3%) in paracetamol group and 37 (52.1%) in tramadol group with patients >35 years being 41 (57.7%) in paracetamol and 34 (47.9%) in tramadol group.

The mean ages for the subjects in the paracetamol group were 30.89 ± 3.50 years, and 30.93 ± 3.82 years in the tramadol group, with the age ranging from 19 to 39 years.

The results, however, showed that there was no significant differences in all the sociodemographic characteristics ($P > 0.05$) in the subjects (paracetamol group and tramadol group).

Severity of pain in paracetamol and tramadol groups at various time intervals

Table 2 shows the mean pain score in paracetamol and tramadol groups at various time intervals. Following the administration of recruitment dose, there was no significant difference in the mean pain score in both groups at recruitment, 30, 60, 120, 180 min, 60 min postpartum, and 120 min postpartum.

Thirty five (24.6%) of all the participants (142) had a rescue dose of the trial drugs. Out of this, 18 (51.4%) were in the paracetamol group and 17 (48.6%) in the tramadol groups. Although, these differences were not statistically significant ($\chi^2 = 0.04$, *P* value = 0.85).

After the administration of first rescue dose, there was no significant difference in the mean pain score in both groups at recruitment, 30 min, 60 min postrescue dose, and 120 min postpartum. However, at 120 min, 180 min postrescue dose, and 60 min postpartum, an obvious increase was observed in the mean pain scores of those in paracetamol group. Although, this difference was not statistically significant (*P* values = 0.36, 0.06, and 0.10, respectively).

Table 1: Sociodemographic characteristics of respondents

Variables	Paracetamol (%)	Tramadol (%)	Chi-square	*P*
Age (years)				
≤30	30 (42.3)	37 (52.1)	1.39	0.24
>30	41 (57.7)	34 (47.9)		
Mean	30.89±3.50	30.93±3.82		
Level of education				
Secondary and below	13 (18.3)	6 (8.5)	2.98	0.08
Tertiary	58 (81.7)	65 (91.5)		
Tribe				
Yoruba	58 (81.7)	62 (87.3)	1.49	0.48
Igbo/Hausa	13 (18.3)	9 (12.7)		
Booking status				
Booked	57 (80.3)	59 (83.1)	0.19	0.66
Unbooked	14 (19.7)	12 (16.9)		

Table 2: Pain score in paracetamol and tramadol groups at various time intervals

Variables	PCM Mean±SD	Tramadol Mean±SD	*t*-test	*P*
Recruitment dose (*N*: 142)				
At recruitment (0 min)	7.97±1.46	7.89±1.45	0.35	0.73
30 min	6.76±1.57	6.93±1.51	–0.65	0.51
60 min	6.51±1.54	6.59±1.52	−0.33	0.74
120 min	6.70±1.31	6.52±1.46	0.75	0.45
180 min	6.98±1.50	6.79±1.56	0.64	0.52
60 min postpartum	1.23±1.43	1.00±1.27	0.83	0.41
120 min postpartum	0.63±1.18	0.58±1.07	0.18	0.86
First rescue dose (*N*: 35)	N: 18	N: 17		
At recruitment (0 min)	8.56±1.15	8.56±1.10	0.00	1.00
30 min	6.89±1.45	7.44±1.38	−1.18	0.25
60 min	7.07±1.27	6.59±1.12	1.13	0.28
120 min	7.25±1.28	6.67±1.44	0.93	0.36
180 min	8.00±1.63	6.25±1.17	2.16	0.06
60 min postpartum	0.70±0.83	1.62±1.81	−1.65	0.10
120 min postpartum	0.07±0.27	0.69±1.11	−1.97	0.05

The mean maternal vital signs scores in paracetamol and tramadol groups at various time intervals

Table 3 shows the maternal vital signs scores in paracetamol and tramadol groups at various time intervals. Following the administration of recruitment dose, there was no significant difference in the mean respiratory rate, pulse rate, systolic blood pressure, and diastolic blood pressure scores in both groups at recruitment, 30, 60, 120, 180 min, 60 min postpartum, and 120 min postpartum ($P > 0.05$).

After the administration of first rescue dose, there was no significant difference in the mean respiratory rate, pulse rate, systolic blood pressure, and diastolic blood pressure scores in both groups at recruitment, 30, 60, 120, 180 min, 60 minutes postpartum, and 120 minutes postpartum ($P > 0.05$).

Labor history of the parturients

Table 4 shows that there was no significant difference in those who had their labor augmented between paracetamol group and tramadol group ($P = 0.10$). Similarly, proportion of those who had prior analgesic was similar in both paracetamol and tramadol groups ($\chi^2 = 0.18$, $P = 0.67$). Among 28 (19.7%) women who had prior analgesic, 27 (96.4%) had 30 mg intramuscular pentazocine while only 1 (3.6%) had 600 mg intramuscular paracetamol. Fourteen (93.3%) women in paracetamol group had pentazocine, while 13 (100.0) were in tramadol group. This difference was also not significant. ($\chi^2 = 0.90$, $P = 0.634$).

Duration of labor and cervical dilatation

Table 5 shows mean duration of labor at various cervical dilatations between paracetamol and tramadol groups. There was no statistically significant difference in mean duration of labor between paracetamol group and tramadol group at 4, 5, 6, and 7 cm cervical dilatations. Also, the mean drug-to-delivery interval was shorter in the paracetamol group as compared to the tramadol group (297 ± 200 vs 307 ± 224 min, $P = 0.73$) but the difference was not statistically significant.

Maternal side effects of the trial drugs

Equal proportion of women with nausea were found in paracetamol group [2 (50%)] and tramadol group [2 (22.2%)], as shown in Table 6. However, vomiting was more in tramadol group [7 (77.8%)] compared to [2 (50%)] paracetamol group. Those found to be drowsy were one in each group. None

Table 3: Mean maternal vital signs in paracetamol and tramadol groups at various times

Variables	Paracetamol Mean±SD	Tramadol Mean±SD	*t*-test	*P*
At recruitment 0 min, *N*=142				
RR/min	23.68±2.31	23.72±2.33	−0.11	0.91
PR/min	85.94±10.26	84.70±12.30	0.65	0.52
BP systolic	117.89±12.97	115.49±11.44	1.17	0.25
BP diastolic	73.80±9.62	74.37±9.82	−0.35	0.73
30 min				
RR/min	23.51±1.94	23.38±2.02	0.38	0.70
PR/min	86.31±6.84	85.18±5.88	1.05	0.29
BP systolic	116.62±10.27	116.90±9.80	−0.17	0.87
BP diastolic	73.38±8.10	73.80±7.24	−0.33	0.74
60 min				
RR/min	23.76±3.14	23.92±2.25	0.34	0.74
PR/min	86.89±6.77	85.83±7.72	0.87	0.39
BP systolic	118.03±10.77	119.01±10.84	−0.54	0.59
BP diastolic	74.51±7.71	74.92±8.62	−0.30	0.77
120 min, *N*=136				
RR/min	23.67±1.93	23.57±1.84	0.33	0.74
PR/min	85.64±7.55	86.29±12.71	−0.36	0.72
BP systolic	117.61±10.46	117.17±10.62	0.24	0.81
BP diastolic	74.18±8.19	75.29±10.21	−0.70	0.49
180 min, *N*=107				
RR/min	23.22±2.18	24.23±2.65	−2.14	0.03
PR/min	86.85±9.21	85.81±7.82	0.63	0.53
BP systolic	118.52±11.88	120.57±11.67	−0.90	0.37
BP diastolic	74.26±5.70	77.55±9.98	−2.10	0.04
First rescue dose 0 min *N*=35				
RR/min	23.18±2.46	24.11±2.32	−1.16	0.26
PR/min	82.12±20.09	89.00±6.30	−1.35	0.18
BP systolic	121.18±11.11	121.67±10.98	−0.13	0.90
BP diastolic	77.06±5.88	77.78±10.60	-0.25	0.81
30 min				
RR/min	23.94±1.95	23.50±2.00	0.66	0.52
PR/min	83.88±5.02	86.33±7.86	−1.11	0.28
BP systolic	121.18±10.54	120.56±11.10	0.17	0.87
BP diastolic	74.12±7.12	77.78±8.78	−1.35	0.19
60 min, *N*=31				
RR/min	24.00±1.57	24.24±1.72	−0.40	0.70
PR/min	85.43±6.20	85.65±6.68	−0.09	0.93
BP systolic	117.86±8.93	119.61±9.72	−0.37	0.71
BP diastolic	72.14±4.26	75.29±11.25	−0.99	0.33
120 min, *N*=20				
RR/min	23.50±2.07	24.33±1.87	−0.94	0.36
PR/min	83.00±6.41	86.33±7.48	−1.03	0.32
BP systolic	118.75±8.35	122.50±9.65	−0.89	0.38
BP diastolic	76.25±7.44	77.50±9.65	−0.31	0.76
180 min, *N*=10				
RR/min	25.00±2.00	23.75±1.98	1.02	0.33
PR/min	81.00±10.00	84.25±11.08	−0.49	0.63
BP systolic	117.50±5.00	126.25±15.98	−1.05	0.32
BP diastolic	75.00±5.774	82.50±14.88	−0.95	0.36
60 min postpartum *N*=116				
RR/min	23.21±3.02	23.21±1.83	0.00	1.00
PR/min	85.69±7.42	86.60±7.98	−0.64	0.52
BP systolic	116.03±10.07	117.59±11.89	−0.76	0.45
BP diastolic	73.10±7.77	73.79±7.45	−0.49	0.63
120 min postpartum				
RR/min	22.59±3.09	22.10±1.81	1.03	0.31
PR/min	84.28±6.68	84.55±7.86	−0.20	0.84
BP systolic	113.79±8.75	117.38±8.49	−2.24	0.03
BP diastolic	72.07±05.85	73.24±6.77	−0.10	0.32

Table 4: Labor history of the parturients

Variables	Paracetamol (%)	Tramadol (%)	Chi-square	*P*
Augmentation				
Yes	36 (52.2)	37 (52.1)	73 (52.1)	0.10
No	33 (47.8)	34 (47.3)	67 (47.9)	
Prior analgesic given				
Yes	15 (21.1)	13 (18.3)	28 (19.7)	0.67
No	56 (78.9)	58 (81.7)	114 (80.3)	

was found to be sleepy in either of the two trial drugs. The results show that there is no significant difference in maternal side effects between paracetamol and tramadol ($\chi^2 = 2.96$, *P* value 0.09).

Patient satisfaction with trial drug 24 h post delivery

Table 7 shows that out of the 142 participants, only 32 (22.5%) expressed their dissatisfaction to the trial drug, out of which 18 (25.4%) were in tramadol group as against 14 (19.7%) in paracetamol group. About half of the respondents, 65 (45.8%) were satisfied out of which 35 (49.3%) were in paracetamol group and 30 (42.3%) were in tramadol group. Forty-five parturients were slightly satisfied with trial drug; 22 (31.0%) were in paracetamol group while 23 (32.4%) were in tramadol group.

The difference in satisfaction between the two trial drugs was, however, not significant ($\chi^2 = 0.91$, *P* value = 0.64).

Mode of delivery of the patients

Table 8 shows mode of delivery of the patients. Equal proportion, 58 (81.7%), of women had vaginal delivery in both groups. One of the women in tramadol group had instrumental vaginal delivery. Similarly, equal proportion of 18.3% of the women in tramadol and paracetamol groups had emergency cesarean section (CS) with only one participant in paracetamol group having emergency CS as a result of fetal distress.

The results showed that there was no significant difference in the mode of delivery of patients in paracetamol and tramadol groups ($\chi^2 = 0.00$, *P* value = 1.0).

Table 5: Mean duration of labor and cervical dilatation (4-7 cm)

Variable	Study group		*F*-test	*P*
	Paracetamol Mean±SD	Tramadol Mean±SD		
Cervical dilation at recruitment (cm)				
4	6.37±8.76	0.89±11.17	1.04	0.38
5	9.49±7.74	4.31±12.03		
6	2.98±10.32	3.42±11.35		
7	5.20±11.79	3.09±11.73		
Mean drug-to-delivery interval in minutes	297±200	307±224	−0.34	0.73

Table 6: Maternal side effects of the trial drugs

Variable	Type of analgesic		*P*
	Paracetamol (%)	Tramadol (%)	
Maternal side effect			
Nausea	2 (50.0)	2 (22.2)	*0.53
Vomiting	2 (50.0)	7 (77.8)	
Sedation			
Alert	70 (98.6)	70 (98.6)	*1.00
Drowsy	1 (1.4)	1 (1.4)	

*Fisher's exact test statistics

Table 7: Patient satisfaction with trial drug 24 hours post delivery

Variable	Type of analgesic		Chi-square	*P*
	Paracetamol (%) *N*=71	Tramadol (%) *N*=71		
Satisfaction				
Satisfied	35 (49.3)	30 (42.3)	0.91	0.64
Slightly satisfied	22 (31.0)	23 (32.4)		
Dissatisfied	14 (19.7)	18 (25.4)		

Table 8: Mode of delivery

Variable	Paracetamol *N*=71	Tramadol *N*=71	Chi-square	*P*
Mode of delivery				
Vaginal delivery	58 (81.7)	58 (81.7)	0.00	1.0
Emergency cesarean	13 (18.3)	13 (18.3)		

Table 8.1: Indications for the emergency cesarean

Indications	Paracetamol (*N*=13)	Tramadol (*N*=13)	Chi-square	*P*
CPD related	11 (84.6%)	13 (100%)	3.39	0.18
Fetal distress	01 (7.7%)	0		
Prolonged labor	01 (7.7%)	0		

Table 9: Neonatal condition

Variable	Type of group		Chi-square	*P*
	Paracetamol *N*=71	Tramadol *N*=71		
Admission to SCBU				
Yes	0 (0)	4 (5.6)	-	*0.12
No	71 (100)	67 (94.4)		
Apgar score at 1 min				
≤7	11 (15.5)	19 (26.8)	2.03	0.15
>7	60 (84.5)	52 (73.2)		
Apgar score at 5 min				
≤7	0 (0.0)	1 (1.4)	-	*1.00
>7	71 (100)	70 (98.6)		

*Fisher's exact test statistic

Neonatal condition

As shown in Table 9, 4 (2.8%) babies were admitted to SCBU and these four were in tramadol group. The indications for admission were fetal macrosomia with perinatal asphyxia, small for gestational age, tachypnea of newborn, and moderate asphyxia following instrumental vaginal delivery.

Out of the 71 deliveries in each group, 60 (84.5%) neonates and 52 (73.2%) had APGAR score more than 7 in the paracetamol and tramadol groups at 1 min, which increased at 5 mins to 71 (100%) in paracetamol group and 70 (98.6%) in tramadol group of the neonates.

Discussion

Results of the current study have shown that the sociodemographic characteristics of pregnant women in paracetamol and tramadol groups were similar at baseline. Booked patients were more than unbooked patients in the study. These results are similar to the study conducted by Kaur Makkar *et al.*[25] (2015), where the researchers compared analgesic efficacy of paracetamol and tramadol for pain relief in active labor in India. Gestational age at labor was not significantly different in both paracetamol and tramadol groups.

The findings from the study showed that mean pain score reduced more in paracetamol group compared to tramadol group up till 60 minutes of drug administration although this was not significant. This was further reflected in slight reduction in mean duration of active labor in paracetamol group compared to tramadol group. Parturients in this study generally responded to both intramuscular analgesics almost the same way. In other words, it was shown in the study that the intramuscular paracetamol was as effective as intramuscular tramadol for providing pain relief during active labor. Analgesic effect of both drugs lasted for 2 hours as determined by the lower pain scores at recruitment, 30, 60, 120 min from the baseline. This is also comparable with

findings from Kaur Makkar *et al.*,[25] where the researchers reported that analgesic effect of both tramadol and paracetamol showed lower pain scores at 10, 20, 30, 60, and 120 min.

In this study, the proportion of those who had augmentation of labor was comparable in both paracetamol and tramadol groups. Similarly, those who had prior analgesia were also comparable in both groups. It is noteworthy to report that the mean duration of labor of those who had prior analgesia was slightly higher than in those who did not receive prior analgesia. One explanation for this is that those who had prior analgesia combined with the trial analgesia experienced more effective labor analgesia.

A study by Arya *et al.*[5] reported that maternal side effects have been observed with tramadol, which include sedation, nausea, vomiting, orthostatic hypotension, and respiratory depression. This study showed that vomiting was observed more with patients in tramadol group but other reported side effects by Arya *et al.* were not noted in this study. Also in agreement to the study by Arya *et al.*, 2003, results from the current study have also shown that more patients in Tramadol group experienced drowsiness. None of the mothers fell asleep after drug administration. Also, neither drugs caused significant changes in maternal blood pressure, pulse rate, and respiratory rate. Kuti *et al.*[26] similarly reported this finding in their study. The present study also showed that mothers were more satisfied with the use of paracetamol during labor. Both drugs, however, showed better safety profile with fewer incidences of vomiting and sedation. It can be adduced from this study that both trial drugs can be safely used in labor.

Furthermore, the mean drug-to-delivery interval was shorter with the use of paracetamol as compared to tramadol. These results are in accordance with Kaur Makkar *et al*.,[25] where mean drug-to-delivery was significantly shorter in paracetamol group, and the study of Elbohoty *et al.*,[14] where the researchers reported mean drug-to-delivery interval was shorter with the use of paracetamol as compared to pethidine. Various studies reported varied mean duration of labor of tramadol and paracetamol. Khooshideh and Shahriari[27] showed a significant shorter duration of labor with the use of tramadol. Whereas, a study by Keskin *et al.*[28] and Kuti *et al.* did not report any significant difference between pethidine and tramadol groups. Viegas *et al.*[24] reported in their study that mean duration of labor was similar between pethidine group and paracetamol group. In this study, there was a reduction in the duration of labor after administration of intramuscular paracetamol; hence total duration of labor was reduced in patients who received paracetamol as compared to tramadol. This could be due to the fact that tramadol causes sedation leading to lesser mobility of women in labor, which could lengthen the labor.

Equal proportion of women in paracetamol and tramadol groups had emergency CSs. Those who had spontaneous vaginal deliveries were also compaed between the two groups. This result is in accordance with the findings of Kaur Makkar *et al.* (2015), where there was no difference found in the incidence of cesarean deliveries with four patients undergoing operative delivery in paracetamol group as compared with four patients in tramadol group. Neonatal outcome was favorable with both paracetamol and tramadol.

Conclusion and Recommendation

The findings from the present study showed that 600 mg intramuscular paracetamol provided similar and modest pain relief in labor compared to 100 mg intramuscular tramadol. Paracetamol was noticed to have fewer maternal adverse effects than tramadol; also the neonatal outcomes of both the drugs were favorable. So from the study, it can be concluded that intramuscular paracetamol is simple, cost-effective, has fewer maternal side effects, readily available, and feasible option as labor analgesics, especially for resource poor settings.

It might be more appropriate if similar study could be repeated by working with the pharmaceutical companies to produce both drugs strength in the same volume to avoid re-constitution.

Financial support and sponsorship

Nil.

Conflicts of Interest

There are no conflicts of interest.

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