

A Randomized controlled trial of intramuscular pentazocine compared to intravenous paracetamol for pain relief in labor at Aminu Kano Teaching Hospital, Kano

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ABSTRACT

Background: Labor is generally considered to be a very painful experience. Epidural analgesia which is the gold standard for labor pain relief is not widely available, affordable, or feasible, especially in our environment. Parenteral opioid analgesics, which are more commonly used, can cause nausea and vomiting in the patient and respiratory depression in the neonate; hence, they cannot be used in all stages of labor. There is thus the need for an alternative analgesic with similar or superior analgesic effect to opioids but without their fetomaternal side effects.

Objectives: The objective of this study was to compare the efficacy of intramuscular (IM) pentazocine and intravenous (IV) paracetamol infusion in relieving labor pain at Aminu Kano Teaching Hospital, Kano.

Study Design: It was a randomized controlled study.

Methodology: One hundred women with singleton uncomplicated pregnancies and spontaneous labor at term were randomly assigned to the study group or control group. Women in the study group received an IV infusion of 1000 mg of paracetamol while women in the control group received a single dose of 30 mg of pentazocine intramuscularly. Labor pain perception was assessed using visual analog scale (VAS) scores at presentation and after delivery while maternal satisfaction assessed using Likert scale, and maternal and fetal complications were recorded after delivery. Statistical analysis was done using computer software SPSS Version 20.0. Chi-square, Fisher's exact test, *t*-test, and Mann-Whitney *U*-tests were used to compare means and proportions as appropriate for statistically significant differences, setting the level of significance (*P* value) at <0.05.

Results: There were no statistically significant differences between the two groups in their sociodemographic characteristics, obstetric characteristics, and labor characteristics. There was also no statistically significant difference in the VAS pain scores between the two groups before administration of the analgesics (*P* = 0.968) and after administration of the analgesics (*P* = 0.225). The maternal satisfaction with pain relief among the patients in the two groups was also found to be similar (*P* = 0.341). Nausea (*P* = 0.002), vomiting (*P* = 0.012), and drowsiness (*P* < 0.001) were significantly higher in the pentazocine group when compared with the paracetamol group. None of the patients in the two groups developed dyspnea during labor, skin rashes, or persistently low systolic blood pressure of <90 mmHg, and none had persistent fetal heart rate abnormalities during labor or appearance, pulse, grimace, activity, and respiration (APGAR) scores <7 at the 1st or 5th min after delivery. However, the mean APGAR score of the neonates at 1 min was significantly higher in the paracetamol group (*P* = 0.033), while there was no difference in the mean APGAR scores of the neonates in the two groups at 5 min after delivery (*P* = 0.152).

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Conclusion: The analgesic efficacy of IV paracetamol was similar to that of IM pentazocine in labor, with similar levels of maternal satisfaction with pain relief, but IV paracetamol was associated with significantly lower rates of adverse effects.

Key words: Labor; pain relief; paracetamol; pentazocine.

Introduction

Labor is generally considered to be a very painful experience. Labor pain has been described as the worst pain that some women may experience in their lifetime. Majority of patients in developing countries do not receive any analgesia in labor. A study conducted in Maiduguri, on desire for pain relief in labor revealed that 81.6% of women would like pain relief in labor, but only 11% received analgesia, with 65.1% describing labor pain as severe.^[1]

Pain results in physiologic effects as well as sensory and emotional responses. Labor pain which results in marked increase in minute ventilation and oxygen consumption during contractions, can cause severe respiratory alkalosis and a left shift of the maternal oxyhemoglobin dissociation curve, thus diminishing oxygen transfer to the fetus. Compensatory hypoventilation between contractions may cause transient maternal hypoxemia, and potentially, fetal hypoxemia. These periods of hypoventilation may be exacerbated by analgesic techniques that result in respiratory depression such as systemic opioid analgesia.^[2] Pain during labor has also been correlated with the development of posttraumatic stress disorder.^[3]

A wide range of methods for pain relief in labor have been described. Nonpharmacological interventions such as hypnosis, biofeedback, intracutaneous or subcutaneous sterile water injection, immersion in water, aromatherapy, relaxation techniques (yoga, music, audio), acupuncture or acupressure, manual methods (massage, reflexology), and transcutaneous electrical nerve stimulation primarily aim to help women cope with pain in labor, whereas the pharmacological interventions such as inhaled analgesia, opioids, nonopioid drugs, local anesthetic nerve blocks, epidural and intrathecal injections of local anesthetics, or opioids (or both) primarily aim to relieve the pain of labor.^[4]

It has been proven that epidural analgesia, when compared with other methods, provides superior analgesia for labor.^[5] However, it is not always feasible, affordable, or available, especially in our environment. Parenteral opioids are popularly used for labor pain relief. Pentazocine, an opioid analgesic, is the drug used for labor pain relief in our center. Opioids may cause nausea and vomiting and delayed gastric emptying which increases risk of aspiration should a general

anesthetic be required in an emergency situation. All opioids cross the placenta. In utero, opioid exposure results in a slower fetal heart rate and decreased beat-to-beat variability. There is also a risk of neonatal respiratory depression as a result of which they cannot be administered in all stages of labor.^[6] There is thus the need for an alternative analgesic with similar or superior analgesic effect to opioids but without their fetomaternal side effects.

Paracetamol is a nonopioid analgesic. Studies examining analgesic efficacy of paracetamol in obstetric cases such as abortion, postoperative pain after Caesarean delivery, and perineal pain after child birth have proposed that paracetamol is an effective analgesic.^[7-10] Paracetamol infusion has been found to have comparable or superior analgesic efficacy to pethidine, tramadol, and placebo when used as a labor analgesic.^[11-14] There is insufficient data in our environment looking at the efficacy and safety of intravenous (IV) paracetamol in relieving labor pain. The purpose of this study is to compare the efficacy of intramuscular (IM) pentazocine and IV paracetamol infusion in relieving labor pain at Aminu Kano Teaching Hospital, Kano. If the analgesic effect of IV paracetamol is found to be comparable or superior to that of pentazocine, then it can provide an opportunity to improve pain management in labor.

Methodology

This was a randomized controlled trial carried out at Aminu Kano Teaching Hospital, Kano, from November 2015 to March 2016 after obtaining approval from the Research Ethics Committee of the hospital.

The sample size was calculated using the formula:^[15]

$$n = \frac{(Z_{\alpha} + Z_{\beta})^2 S^2}{d^2}$$

Forty-four women were required in each group to achieve a power of 95% and Type 1 error of 0.05. To make up for those who could later be excluded from the study, 10% was added, giving a minimum sample size of 48. This was rounded up and 50 patients were recruited in each group. The data were collected over 5 months.

All pregnant women who presented with spontaneous onset of labor, a singleton live fetus at term in active phase of labor with cervical dilatation of 4–6 cm and consented to participate in the study were included in the study. The patients who were excluded were those who did not consent to participate and those who presented with preterm labor, multiple gestation, fetal heart rate abnormalities or intrauterine fetal death, previous caesarean section, fetal presentation other than cephalic as well as malposition of the fetal head, medical disorders including history of cardiac, liver and renal disease, history of hypersensitivity to pentazocine or paracetamol, complications such as antepartum hemorrhage, polyhydramnios, premature rupture of membranes, or use of any kind of analgesia before recruitment.

Sampling technique and randomization

A single-blind simple random sampling method was used in this study to recruit the subjects. Group A was the study group and the patients in that group received IV infusion of paracetamol. Group B was the control group and the patients in that group received IM pentazocine. Patients were assigned to either of the two groups by balloting. Two sets of 50 opaque envelopes containing pieces of paper labeled as A or B were prepared by a research assistant who did not participate in data collection. All 100 envelopes were mixed thoroughly and placed in a box in the labor ward. An envelope was given to each consecutive patient who consented and satisfied the inclusion criteria. The researcher did not know which group the patient belonged to before the end of the study.

Data collection techniques and tools

Eligible women who presented to the labor ward in labor were consecutively recruited into the study until the required sample size is obtained. The patients were recruited by the researcher and the two trained research assistants. The participants signed a written consent before participation. At the time of admission history was taken, antenatal records of the patient were reviewed, and clinical examination as well as a bed side ultrasound scan were done to exclude any of the exclusion criteria. Patients who fulfilled the inclusion criteria were recruited. The sociodemographic data (age, marital status, tribe, religion, occupation, and educational status) and obstetric data of the patients (parity, last menstrual period, estimated date of delivery, epidural-general anesthesia, use of analgesia in a previous pregnancy) were recorded in the questionnaire. The initial pain perception was also assessed using the VAS at admission before randomization and recorded in millimeters. All patients had IV access with a size 18 G cannula secured and artificial rupture of membranes done at admission if there was no contraindication. Patients were recruited in the admission room, then taken to the nurse

in the delivery room who then did the randomization and drug administration. An envelope was opened by a nurse and the analgesic was administered. The nurse then recorded the patient's serial number and group in a book that was provided and kept in the labor ward till the end of the data collection.

Patients in Group A (study group) received an IV infusion of 1000 mg paracetamol in 100 ml solution over 15 min using a standard gravity-dependent IV infusion set, in which each 20 drops give 1 ml (infusion rate was about 130 drops/min). At the same time, patients in Group B received 30 mg of IM pentazocine injection in the gluteal region. Only a single dose was used in both groups after randomization and repeat doses were not administered. A partograph was filled at admission for all patients, and monitoring was commenced 20 min later to allow time for randomization and drug administration.

During the first stage of labor, the fetal heart rate was monitored using intermittent auscultation with a sonicaid every 15 min (during and immediately after uterine contractions). Persistent fetal heart rate abnormalities were defined in this study as the presence of fetal tachycardia (heart rate more than 160 beats/min) or bradycardia (heart rate < 110 beats/min) or fetal heart rate decelerations lasting for more than 30 min.

Maternal vital signs were monitored hourly, uterine contractions were also monitored hourly, and pelvic examination was done 4 hourly. Fetal heart rate was monitored every 5 min in the second stage of labor with the same sonicaid. The third stage of labor was managed actively in all patients.

A resuscitation tray was made available in the labor ward containing naloxone, promethazine, IV fluids, syringes, and infusion giving sets. Furthermore, a neonatologist was to be present at delivery for neonatal resuscitation where persistent fetal heart rate abnormalities were found.

The severity of labor pain and maternal satisfaction with pain relief was assessed 1 h after delivery in both groups. Again, the severity of the labor pain was assessed using the VAS and the score recorded in millimeters, while maternal satisfaction with pain relief was assessed in both groups using the Likert scale. Appearance, pulse, grimace, activity, and respiration (APGAR) score of neonate in 1 and 5 min, presence of persistent fetal heart rate abnormalities during labor, and the duration of labor were also determined after delivery and recorded in the questionnaire. The incidence of maternal complications including nausea, vomiting, dyspnea, skin rash, and systolic blood pressure <90 mmHg were

recorded in each group 2 h after delivery. The researcher and four trained assistants (resident doctors in the Department of Obstetrics and Gynecology), all of whom did not know which drug was administered to the patient by the nurse, monitored the labor, and administered the questionnaire. The patients group was obtained from the record book and recorded on her questionnaire before data analysis.

All patients who eventually had augmentation of labor, instrumental delivery, or Caesarean section were to be excluded from the study, but all had normal vaginal delivery and none was excluded from the study.

Outcome measures

- Maternal: Maternal labor pain score, maternal satisfaction with pain relief, drowsiness during labor, nausea and vomiting in labor
- Fetal and neonatal: Persistent fetal heart rate abnormalities, APGAR score <7 at 1 min, and APGAR score <7 at 5 min.

Statistical analysis

Information obtained at the end of the study was processed using the SPSS 20.0 statistical program (IBM Corp. Released 2011, IBM SPSS Statistics for Windows, Version 20.0 Armonk, NY, USA). Categorical data were expressed as frequencies and percentages and analyzed by Chi-square and Fisher's exact tests. Normally distributed continuous data were described using mean and standard deviation and was analyzed using Student's *t*-test, while continuous variables that were not normally distributed were analyzed using Mann-Whitney *U*-test. Paired *t*-test was used to analyze the difference in the mean VAS scores in each group before and after administration of the analgesic to determine whether the reduction in the pain score was statistically significant. The results were presented in tables. $P < 0.05$ was determined to be statistically significant.

Results

The study was carried out in the labor ward of Aminu Kano Teaching Hospital, Kano, from November 2015 to March 2016. None of the patients was withdrawn from the study after recruitment, and all had vaginal deliveries. Relevant data were collected and analyzed in all the patients.

Table 1 shows the sociodemographic characteristics of the patients. The mean age of the patients in the study group was 26.9 ± 4.76 years while the mean age of patients in the control group was 27.1 ± 4.35 years, the difference was not statistically significant ($P = 0.827$). Generally, there were no statistically significant differences in the sociodemographic characteristics of the patients in the two groups.

Table 1: Sociodemographic characteristics of patients

Variable	Group A (n=50)	Group B (n=50)	Test	P
Mean age \pm SD (years)	26.9 \pm 4.76	27.1 \pm 4.35	$t = -0.22$	0.827
Tribe, n (%)				
Hausa	24 (48.0)	25 (50.0)	$\chi^2 = 2.46$	0.653
Fulani	9 (18.0)	6 (12.0)		
Yoruba	8 (16.0)	5 (10.0)		
Igbo	6 (12.0)	10 (20.0)		
Others*	3 (6.0)	4 (8.0)		
Religion, n (%)				
Islam	39 (78.0)	32 (64.0)	$\chi^2 = 2.38$	0.123
Christianity	11 (22.0)	18 (36.0)		
Occupation, n (%)				
Housewife	21 (42.0)	23 (46.0)	$\chi^2 = 2.87$	0.580
Trader/business woman	11 (22.0)	8 (16.0)		
Teacher/lecturer	6 (12.0)	11 (22.0)		
Civil servant	5 (10.0)	3 (6.0)		
Others**	7 (14.0)	5 (10.0)		
Education, n (%)				
Quranic education	3 (6.0)	1 (2.0)	$\chi^2 = 2.38$	0.497
Primary education	2 (4.0)	4 (8.0)		
Secondary education	19 (38.0)	23 (46.0)		
Tertiary education	26 (52.0)	22 (44.0)		

*Others - Nupe, Ebara, Kanuri, Ijaw; **Others - banker, hair dresser, tailor; SD - Standard deviation

Table 2 shows the obstetric and labor characteristics of the patients. There were no statistically significant differences between the two groups in terms of their obstetric and labor characteristics in this study.

Table 3 shows the pain perception scores of the patients and the maternal satisfaction with pain relief. The mean VAS scores at admission before administration of the analgesic was 97.5 ± 4.52 mm in the study group and 97.6 ± 5.28 mm in the control group, and these scores were statistically similar ($P = 0.968$). The mean VAS scores after administration of the analgesic was 77.6 ± 10.59 mm in the study group and 75.3 ± 9.84 mm in the control group, and these scores were also statistically similar ($P = 0.225$). In the study group, administration of IV paracetamol was associated with a reduction in the mean VAS pain score from 97.5 ± 4.52 to 77.6 ± 10.59 mm, and this reduction in pain score was statistically significant ($P < 0.001$). Similarly, administration of IM pentazocine in the control group was associated with a reduction in the mean VAS pain score from 97.6 ± 5.28 to 75.3 ± 9.84 mm and the difference was statistically significant ($P < 0.001$). The mean differences between the VAS scores before and after analgesic administration in the two groups were 19.0 ± 9.08 and 22.3 ± 8.48 mm in the study and control groups, respectively, and there was also no statistically significant difference between the two groups ($P = 0.179$).

The maternal satisfaction, as assessed by the Likert scale, showed that most of the patients in the two groups were somewhat satisfied with the pain relief provided by the analgesic that was administered (54.0% in the study group and 62.0% in the control group), the difference was not statistically significant ($P = 0.341$). Generally, there were no statistically significant differences in the pain perception and maternal satisfaction with pain relief in patients between the two groups.

Table 4 shows the maternal and the fetal outcome. Nausea ($P = 0.002$), vomiting ($P = 0.012$), and drowsiness ($P < 0.001$) were significantly higher in the pentazocine group when compared with the paracetamol group. None of the patients in the two groups developed dyspnea during labor, skin rashes, or persistently low systolic blood pressure of <90 mmHg, and none had persistent fetal heart rate

abnormalities during labor or APGAR scores of <7 at the 1st or 5th min after delivery. However, the mean APGAR score of the neonates at 1 min was significantly higher in the paracetamol group ($P = 0.033$), while there was no difference in the mean APGAR scores of the neonates in the two groups at 5 min after delivery ($P = 0.152$).

Discussion

In this study, the difference in the pain perception following administration of the analgesic during labor between the two groups was not statistically significant as shown by statistically similar mean VAS scores. This shows that the efficacy of IV paracetamol infusion during labor is similar to that of IM pentazocine in providing pain relief. Generally, there is paucity of studies in which IV paracetamol was compared with IM pentazocine for pain relief during labor.

Table 2: Obstetric and labor characteristics of patients

Variable	Group A (n=50)	Group B (n=50)	Test	P
Mean parity±SD	2.5±1.75	2.3±1.52	$t=0.61$	0.543
Mean gestational age (weeks)	39.2±1.04	39.3±0.98	$t=-0.50$	0.621
Median duration of labor and IQR (min)	284.0/5 (257.75-317.00)	284.0 (252.50-320.25)	$U=1210.00$	0.783
Mean EBL (mL)	248.0±74.20	250.0±69.25	$t=-0.14$	0.889
Mean fetal weight (kg)	3.2±0.24	3.1±0.25	$t=0.82$	0.415

IQR - Interquartile range; SD - Standard deviation; EBL - Estimated blood loss

Table 3: Pain perception and maternal satisfaction with pain relief

Variable	Group A (n=50)	Group B (n=50)	Test	P
Mean VAS scores before analgesia (mm)	97.5±4.52	97.6±5.28	$t=-0.041$	0.968
Mean VAS scores after analgesia (mm)	77.6±10.59	75.3±9.84	$t=1.14$	0.255
Mean difference in VAS scores (mm)	19.9±9.08	22.3±8.48	$t=-1.35$	0.179
Maternal satisfaction, n (%)				
Somewhat dissatisfied	2 (4.0)	0	$\chi^2=3.35$	0.341
Neither dissatisfied or satisfied	11 (22.0)	7 (14.0)		
Somewhat satisfied	27 (54.0)	31 (62.0)		
Very satisfied	10 (20.0)	12 (24.0)		

VAS - Visual analog scale

Table 4: Maternal and fetal outcome

Variable	Group A (n=50)	Group B (n=50)	Test	P
Nausea, n (%)				
Yes	2 (4.0)	13 (26.0)	$\chi^2=9.49$	0.002*
No	48 (96.0)	37 (74.0)		
Vomiting, n (%)				
Yes	0	6 (12.0)	Fisher's exact test	0.012*
No	50 (100.0)	44 (88.0)		
Drowsiness, n (%)				
Yes	0	17 (34.0)	Fisher's exact test	$<0.001^*$
No	50 (100.0)	33 (66.0)		
Mean APGAR scores				
At 1 min	8.1±0.61	7.8±0.58	$t=2.17$	0.033*
At 5 min	9.3±0.53	9.1±0.58	$t=1.44$	0.152

*Statistically significant

However, other studies have compared the analgesic efficacy of IV paracetamol to other opiates or placebo in labor. The analgesic efficacy of IV paracetamol infusion in labor has been found to be superior to placebo, IM pethidine, and tramadol in different studies but comparable to that of IV pethidine.^[11-14] The analgesic efficacy of IV paracetamol in labor was comparable to that of IM pentazocine probably because of the pharmacology of IV paracetamol. When administered intravenously, its onset of action is 5 min which is faster than the 15–20 min for IM pentazocine.^[16,17] It also has a longer duration of action than IM pentazocine (4–6 h compared with 3 h).^[16,17] Furthermore, IV administration of paracetamol avoids the first-pass effect in the liver and leads to higher tissue concentrations of the drug, possibly enhancing its analgesic effect.^[18]

These drugs reduced pain during labor, but not as much as epidural analgesia.^[19] Epidural analgesia has the following advantages, provides superior pain relief in first and second stages of labor, facilitates patient cooperation during labor and delivery, provides anesthesia for episiotomy and instrumental delivery, allows extension of anesthesia for caesarean delivery and avoids opioid-induced maternal and neonatal respiratory depression from IV opioids. Besides providing analgesia in labor epidural analgesia may facilitate atraumatic vaginal delivery of twins, preterm neonates, and neonates with breech presentation. It also helps control blood pressure in women with preeclampsia by alleviating labor pain, and it blunts the hemodynamic effects of uterine contractions and the associated pain response in patients with other medical complications.^[19]

The maternal satisfaction with labor analgesia, as assessed by the Likert scale in the two groups, showed no statistically significant difference. There is paucity of studies in which maternal satisfaction with pain relief in labor was studied using IV paracetamol and IM pentazocine. The similar maternal satisfaction rates in the two groups obtained in this study is in contrast with the findings from a Cochrane review, in which maternal satisfaction with labor pain relief was compared as a secondary outcome measure between opioid and nonopioid analgesics.^[20] In that study, women who had nonopioid analgesics were less likely to be satisfied with pain relief compared with women who had opioids.^[20] This contrast may be because the majority of studies included in that review were conducted over 30 years ago and the studies were at unclear risk of bias as noted by the authors of the review.^[19] Furthermore, the nonopioid analgesics used in the studies were nonsteroidal anti-inflammatory drugs, and none used IV paracetamol infusion. In both arm of this study, significant proportion of the subjects (54% and 62%) was somewhat satisfied with the pain relief achieved with the

IV paracetamol and the IM pentazocine, this implied that the efficacy of both agents studied is not excellent.

Maternal nausea, vomiting, and drowsiness all occurred more frequently in the pentazocine group than in the paracetamol group. None of the patients in either group developed dyspnea during labor, skin rashes, or low systolic blood pressure below 90 mmHg. This is similar to the findings in one study in which IV paracetamol was compared with IV pethidine.^[12] The study showed 64% of the patients in the pethidine group developed maternal adverse effects such as vomiting, dizziness, and blurring of vision, while none of the patients in the paracetamol group developed these complications.^[12] In another study, maternal adverse effects were compared between patients who received IV paracetamol and a placebo, and none of the patients who received paracetamol developed any maternal adverse effects.^[13] The findings from these studies further confirmed the safety and tolerability of paracetamol. Other studies, however, did not find any significant difference in the occurrence of adverse maternal side effects when IV paracetamol was used compared with other opiates for labor analgesia.^[11,14] In one of these studies where IV paracetamol and IM pethidine were used, they reported no difference in the rate of adverse maternal side effects.^[11] This was most likely because all patients in that study received IV promethazine and IV hyoscine before randomization and administration of the analgesic, and this could have reduced the incidence of nausea and vomiting in the pethidine group. Furthermore, the overall complication rates were reported in that study; the incidence of each of the complications was not mentioned; and rate of each of these complications were not compared between the two groups. Furthermore, the study did not report on the rate of dizziness or drowsiness among the patients, which could be expected to be higher in the pethidine group due to synergistic effect of pethidine and pentazocine that could worsen maternal drowsiness, and therefore potentially increase the rate of maternal adverse effects in the pethidine group. Another study in which IV paracetamol was compared with IM tramadol for pain relief in labor also reported no significant difference in the rates of maternal adverse effects between the two groups.^[14] The higher incidence of nausea and vomiting in the pentazocine group was due to the opiate effect of pentazocine. The exact mechanism by which it causes these symptoms is unknown, but it is thought to be through direct stimulation of the chemoreceptor trigger zone, increased vestibular sensitivity, and delayed gastric emptying.^[21] Paracetamol does not have these effects due to different mechanisms of action.^[22-25] Furthermore, pentazocine was associated with higher incidence of drowsiness because it inhibits the ascending pain pathways, which causes alteration in response to pain,

producing analgesia, and sedation.^[16] Again, paracetamol is not associated with sedation due to its different mechanisms of action.

None of the fetuses in the two groups developed persistent fetal heart rate abnormalities during labor. Furthermore, none of the neonates in the two groups had an APGAR score <7 in the 1st or 5th min after delivery. However, the mean APGAR score at 1 min though it was above 7 was significantly lower in the pentazocine group than in the paracetamol group. There was no significant difference in the mean APGAR score of the neonates 5 min after delivery in the two groups. This is similar to the findings in a similar study in which IV paracetamol and IV pethidine were used.^[12] They also found a significantly lower mean 1st min APGAR score in the pethidine group compared to the paracetamol group, but there was no significant difference in the mean 5th min APGAR scores between the two groups.^[12] Other studies found no difference in the mean APGAR scores of the neonates both at 1 min and at 5 min between the two groups when IV paracetamol was compared with other opiates or placebo.^[11,13,14] The 1 min APGAR score is a reflection of how well the baby tolerated the birthing process and the *in utero* environment while the 5 min APGAR score reflects how well the baby is doing after birth following resuscitation. Opiates cross the placental barrier and can cause respiratory depression in the neonate after birth, and this could explain the lower mean 1st min APGAR score in the pentazocine group.^[6] Paracetamol, though it also crosses the placenta barrier, has not been shown to have any adverse effect on the fetus when used in standard dose in healthy pregnant women at term.^[26]

Conclusion

In conclusion, this study showed that the efficacy of IV paracetamol was comparable to that of IM pentazocine for pain relief during normal labor. Furthermore, the maternal satisfaction with pain relief during labor was similar when IV paracetamol was compared with IM pentazocine. However, IV paracetamol was associated with significantly lower maternal adverse effects and significantly higher APGAR scores at 1 min after delivery though the APGAR scores at 5 min after delivery were similar to those obtained following administration of IM pentazocine. These findings show that IV paracetamol is not only as effective as IM pentazocine in providing pain relief in labor but also safer for the mother and the baby.

Limitations

Pain perception and maternal satisfaction were difficult to measure because they are subjective. Furthermore,

confounding factors such as maternal anxiety, which could have influenced pain perception, could not be controlled for.

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Conflicts of interest

There are no conflicts of interest.

References

1. Audu B, Yahaya U, Bukar M, El-Nafaty A, Abdullahi H, Kyari O. Desire for pain relief in labour in Northeastern Nigeria. *J Public Health Epidemiol* 2009;1:53-7.
2. Wong CA. Advances in labor analgesia. *Int J Womens Health* 2010;1:139-54.
3. Soet JE, Brack GA, DiIorio C. Prevalence and predictors of women's experience of psychological trauma during childbirth. *Birth* 2003;30:36-46.
4. Jones L, Othman M, Dowswell T, Alfirevic Z, Gates S, Newburn M, *et al.* Pain management for women in Labour: An overview of systematic reviews. *Cochrane Database Syst Rev* 2012;(3):CD009234.
5. Anim-Somuah M, Smyth R, Howell C. Epidural versus non-epidural or no analgesia in labour. *Cochrane Database Syst Rev* 2005;19(40):CD000331.
6. Ullman R, Smyth LA, Burns E, Mori R, Dowswell T. Parenteral opioids for maternal pain relief. *Cochrane Database Syst Rev* 2010;(9):CD007396.
7. Tzortzopoulou A, Mc Nicol ED, Cepeda MS, Francia MB, Farhat T, Schumann R. Single dose intravenous propacetamol or intravenous paracetamol for post operative pain. *Cochrane Database Syst Rev* 2011;(10):CD007126.
8. Penney G. Treatment of pain during medical abortion. *Contraception* 2006;74:45-7.
9. Kiliçaslan A, Tuncer S, Yüceaktas A, Uyar M, Reisli R. The effects of intravenous paracetamol on postoperative analgesia and tramadol consumption in cesarean operations. *Agri* 2010;22:7-12.
10. Foroughipour A, Firuzeh F, Ghahiri A, Norbakhsh V, Heidari T. The effect of perineal control with hands-on and hand-poised methods on perineal trauma and delivery outcome. *J Res Med Sci* 2011;16:1040-6.
11. Abdollahi MH, Mojibian M, Pishgahi A, Mallah F, Dareshiri S, Mohammadi S, *et al.* Intravenous paracetamol versus intramuscular pethidine in relief of labour pain in primigravid women. *Niger Med J* 2014;55:54-7.
12. Elboholy AE, Abd-Elrazek H, Abd-El-Gawad M, Salama F, El-Shorbagy M, Abd-El-Maeboud KH. Intravenous infusion of paracetamol versus intravenous pethidine as an intrapartum analgesic in the first stage of labor. *Int J Gynaecol Obstet* 2012;118:7-10.
13. Abd-El-Maeboud KH, Elboholy AE, Mohammed WE, Elgamel HM, Ali WA. Intravenous infusion of paracetamol for intrapartum analgesia. *J Obstet Gynaecol Res* 2014;40:2152-7.
14. Lallar M, Anam HU, Nandal R, Singh SP, Katyal S. Intravenous paracetamol infusion versus intramuscular tramadol as an intrapartum labor analgesic. *J Obstet Gynaecol India* 2015;65:17-22.
15. Zhong B. How to calculate sample size in randomized controlled trial? *J Thorac Dis* 2009;1:51-4.
16. Pentazocine Hydrochloride Prescribing Information. Version 2.0. Available from: http://www.druglib.com/druginfo/talwin/description_pharmacology/. [Last accessed on 2014 Jun 10].
17. Woo A. intravenous Paracetamol. Available from: <http://www anaesthesiologyUK.Com>. [Last accessed on 2014 Jun 10].
18. Jahr JS, Lee VK. Intravenous acetaminophen. *Anesthesiol Clin*

- 2010;28:619-45.
19. Hemant KS, Alex M. labour and delivery, *Analgesia Regional and Local*. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/12540646>. [Last accessed on 2014 Jun 14].
 20. Othman M, Jones L, Neilson JP. Non-opioid drugs for pain management in labour. *Cochrane Database Syst Rev* 2012;(7):CD009223.
 21. Redmond M, Glass P. Opiate-induced nausea and vomiting: What is the challenge? *Anesth Analg* 2005;101:1341-2.
 22. Kumpulainen E, Kokki H, Halonen T, Heikkinen M, Savolainen J, Laisalmi M. Paracetamol (acetaminophen) penetrates readily into the cerebrospinal fluid of children after intravenous administration. *Pediatrics* 2007;119:766-71.
 23. Chandrasekharan NV, Dai H, Roos KL, Evanson NK, Tomsik J, Elton TS, *et al.* COX-3, a cyclooxygenase-1 variant inhibited by acetaminophen and other analgesic/antipyretic drugs: Cloning, structure, and expression. *Proc Natl Acad Sci U S A* 2002;99:13926-31.
 24. Ottani A, Leone S, Sandrini M, Ferrari A, Bertolini A. The analgesic activity of paracetamol is prevented by the blockade of cannabinoid CB1 receptors. *Eur J Pharmacol* 2006;531:280-1.
 25. Alloui A, Chassaing C, Schmidt J, Ardid D, Dubray C, Cloarec A, *et al.* Paracetamol exerts a spinal, tropisetron-reversible, antinociceptive effect in an inflammatory pain model in rats. *Eur J Pharmacol* 2002;443:71-7.
 26. Isbister GK, Bucens IK, Whyte IM. Paracetamol overdose in a preterm neonate. *Arch Dis Child Fetal Neonatal Ed* 2001;85:F70-2.