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Original Research Article

Intravenous Paracetamol versus Tramadol in Labor Analgesia: A Randomised Prospective Study

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ABSTRACT

Background
Women experience varied levels of agony during labor and delivery and each woman's labor may be extremely different. Since many women and their doctors firmly thought that labour pain was a normal and essential part of childbirth, the analgesic treatments were contentious.

Aims and objectives
To compare the effectiveness and side effects of an intravenous infusion of 50 mg of tramadol hydrochloride vs. 1 g of paracetamol for intrapartum analgesia.

Methods
The study was conducted in low-risk, antenatal term inpatients admitted for safe confinement in the labor room of the Department of Obstetrics and Gynaecology, Malabar Institute of Medical Sciences, Calicut, during the study period. They were randomly assigned to receive either 100 ml of intravenous infusion containing 1 g of paracetamol over 15 minutes or intravenous injection of 10 ml of normal saline containing 50 mg of tramadol over 10 minutes.

Results
Pain score at 15 min, 1 hr., 2 hr., 3 hr., and 4 hr., showing statistically significant variation between groups. Labor duration showing marked variation between groups with a mean duration of 3 hours in the paracetamol group compared to 4.9 hours in the tramadol group. The rate of caesarean section is significantly higher in the tramadol group [42%] as compared to the paracetamol group [22%]. Comparison of APGAR at 1 minute and 5 minutes shows a statistically significant higher value in the paracetamol group. Rate of NICU admission higher in tramadol group [18%].

Conclusion
1g intravenous paracetamol is a significantly better analgesic than 50 mg intravenous tramadol in providing intrapartum analgesia.

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Keywords: Paracetamol, Tramadol, Intrapartum Analgesia, Labor Duration, APGAR, VAS Score.

INTRODUCTION

The pain of childbirth is likely to be the most severe pain that a woman experiences during her lifetime. Many women, especially nulliparas, rate the pain of labor as very severe or intolerable.[1,2] The pain of labor and delivery varies among women, and each labor of an individual woman may be quite different. In the middle of the 1800s, pharmacological treatment for labor pain was introduced. Since many women and their doctors firmly thought that labor pain was a normal and essential part of childbirth, these analgesic treatments were contentious.[3,4]

For instance, a study of 100 women having vaginal deliveries found that a sense of control and involvement in the decision-making process was linked to satisfaction with pain relief.[5] According to these results, in order to improve mother satisfaction, women should be involved in the decision-making process for all aspects of childbirth, including pain management. This can be achieved by teaching pregnant women pain management strategies before labor starts. This will allow women to thoroughly consider their alternatives before labor starts, as it can be challenging to make logical decisions when they are experiencing physical and mental distress.[6]

The provision of regional labor analgesia is now regarded in many nations as a reflection of conventional obstetric treatment. According to the 2001 report, up to 60% of large US maternity clinics accept epidurals. According to the UK's National Health Services Maternity Statistics during 2005–2006, one-third of parturients opted for epidural analgesia.[7] With the exception of a few facilities that provide a complete labor analgesia program, there is still a dearth of knowledge and acceptability of pain-relieving choices for laboring women in our nation.[8] Therefore, the purpose of this study was to assess the effectiveness and side effects of an intravenous infusion of 50 mg of tramadol hydrochloride vs. an intravenous infusion of 1 g of paracetamol for intrapartum analgesia.

MATERIALS AND METHODS

The current prospective randomized controlled study was conducted in low-risk, antenatal term inpatients admitted for safe confinement in the labor room of the Department of Obstetrics and Gynaecology, Malabar Institute of Medical Sciences, Calicut, for a period of 1.5 years—from September 1st, 2014, to March 31st, 2016, on 100 antenatal patients considering the inclusion and exclusion criteria.

Inclusion Criteria

a. Low risk parturients aged 18-35 years
b. Spontaneous/induced onset of labor at term (37-42 weeks of gestation) with cervical dilatation of 3-6 cm
c. Single live fetus in cephalic presentation

Exclusion Criteria

a. Clinical evidence of cephalo-pelvic disproportion.
b. Grand multipara > 5^{th} gravida
c. Use of any kind of analgesia before recruitment to the study
d. Fetal distress at the time of admission
e. Previous history of hypersensitivity to either drug
f. Medical diseases especially hepatic and renal diseases
g. Previous caesarean section

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Sample Size Calculation

Sample size was calculated using the following formula

$n = 2 [Z\alpha + Z\beta]^2 \sigma^2/d^2$

Where α = probability of type 1 error

β = probability of type 2 error

σ = Standard deviation

d =difference between groups in improvement of VAS score

$n= 2[1.96 + 0.84]^2 7^2/4^2$

n = 50 / group, where 1.96 is the Z value corresponding to a type 1 error of 5% and 0.84 is the Z value corresponding to a type 2 error of 20%, so that power is 80%. We had taken the standard deviation as 7 and the difference in improvement of the VAS score between the treatment group as significant. It was determined that the study would require a minimum sample size of 50 women in each group. Hence it was decided to conduct the study in 100 parturients in labor after considering inclusion and exclusion criteria.

Study Procedure

The study was conducted in the low-risk antenatal term inpatients admitted for safe confinement in the study period of 1.5 years after considering the exclusion criteria. Good uterine contractions, cervical dilatation of at least 3 cm, and cervical effacement of at least 60% were considered indicators of the active phase of labor.

The hospital's ethical committee granted ethical clearance, and each individual gave their informed consent. Following that, they were randomised to receive either an intravenous injection of 10 ml of normal saline containing 50 mg of tramadol over 10 minutes or 100 ml of intravenous infusion containing 1 g of paracetamol over 15 minutes.

Paracetamol was a single bottle of 100 ml of strength 10 mg/ml manufactured by Bristol Myers Squibb India Private Ltd., available at a cost of Rs. 280. Tramadol was a single vial of 1 ml containing 50 mg of tramadol hydrochloride, manufactured by Biochem Pharmaceuticals under the brand name Biotram, available at a cost of Rs. 13.60.

Randomization was done by computer-generated random alphabets. For this, alphabets A and B were generated randomly using the command Rand between (A; B) in an Excel spreadsheet, and the patients were allotted to either of the treatment groups accordingly: A to the paracetamol group and B to the tramadol group. Master charts were prepared according to this. On analysis, our randomization seemed to have produced balanced groups.

Intervention

The following were the two groups that were assigned at random: All women enrolled in the study underwent a thorough history, general physical examination, obstetric examination (including vaginal examination), and all required investigations. Group A consisted of antenatals in labor receiving intravenous paracetamol 1 g, while Group B consisted of antenatals in labor receiving intravenous tramadol 50 mg. A partogram was used to track labor. A non-stress test was used to monitor the fetus.

Labor was followed up according to the hospital’s protocols with artificial rupture of membranes and subsequent application of an oxytocin infusion if there are fewer than 3 contractions in 10 minutes, each lasting less than 40 seconds. Participants reported pain in few intensity on a Visual Analogue Scale bounded by no pain and the worst pain immediately after receiving the study

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drug and at 15 min, 1 hour, 2 hours, 3 hours and 4 hours after drug administration. Pain assessment was performed by one person who had no role in patient enrollment and was blind to drug administration. Pain scores up to 4 were considered mild, 5-7 as moderate, and >8 as severe. Participants not delivered within 4 hours and still needing analgesia were given a single further infusion of paracetamol so that the cumulative dose does not exceed 3g/24 hours, whereas those in the tramadol group would be given tramadol as dictated by their case. The second dosage was given only after patient consent. If the patient was not satisfied with the analgesic effect of the drug provided, other options of rescue analgesia would be given.

However, none of the patients in both groups of our study demanded another rescue analgesic. Every 30 minutes after the medication injection and before the analgesic was administered, homeodynamic variables were noted. Non-invasive pulse oximetry and blood pressure monitoring were used to keep an eye on the parturients. A systolic blood pressure reading below 70–80% of baseline readings and/or an absolute value below 100 mmHg were considered maternal hypotension, while a respiratory rate below 8 was considered respiratory depression. A neonatologist used APGAR scores at one and five minutes to evaluate the newborn, and any other issues were noted as well. Adverse events that were spontaneously observed and reported were noted in both the mother (dizziness, tachycardia, dyspnoea, vomiting, blurred vision, dry mouth, and significant changes in blood pressure (≥30 mm Hg systolic and ≥15 mm Hg diastolic)) and in the foetus and neonate (non-reassuring CTG, including foetal tachycardia, low APGAR score at 1 and 5 minutes and the need for admission to the intensive care unit). Additionally, the length of labor was computed. Postpartum maternal and neonatal liver enzymes [SGOT, SGPT] were done to ensure safety in the paracetamol group. Funding for the drugs as well as post-partum maternal and neonatal liver enzymes [in case of the paracetamol group], was done by the principal investigator.

Statistical Methods

The findings were presented in the form of mean ± SD. Student's t-test was used for quantitative analysis. The Chi-square test was employed for qualitative analysis. The Mann-Whitney U-test was used to compare non-parametric data. Data presentation and statistical analysis were conducted using SPSS version 16.0 [IBM, Armink and NY, USA] and Excel 2007 bp [Microsoft, Redmint, WA, USA]. P-values below 0.05 were regarded as significant.

RESULTS

Outcome

Primary Outcome

To study the efficacy of the drug to supply adequate analgesia as measured by a change in visual analogue scale pain intensity at various times after drug administration.

Secondary Outcome

- To assess
- Need for additional rescue analgesia.
- The presence of adverse maternal or fetal events in both groups.
- Labor duration difference between both groups.
- Number of cases that went in for LSCS due to prolonged labor in both groups

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Age (in years)	Paracetamol		Tramadol	
	Count	Percentage	Count	Percentage
<=20	3	6.0	2	4.0
21 - 25	21	42.0	17	34.0
26 - 30	17	34.0	23	46.0
>30	9	18.0	8	16.0
Mean ± SD	26.2 ± 4.5		27 ± 3.9	

Table 1: Comparison of Age Distribution Based on Drugs

Age of the patients did not differ significantly between the groups.

Gravida	Paracetamol		Tramadol		χ^2	p
	Count	Percentage	Count	Percentage		
1	20	40.0	20	40.0	2.11	0.550
2	19	38.0	17	34.0		
3	11	22.0	11	22.0		
4	0	0.0	2	4.0		

Table 2: Comparison of Gravida Based on Drugs

Gravida score was distributed almost equally between groups; the 'p' value obtained by the chi-square test was 0.55.

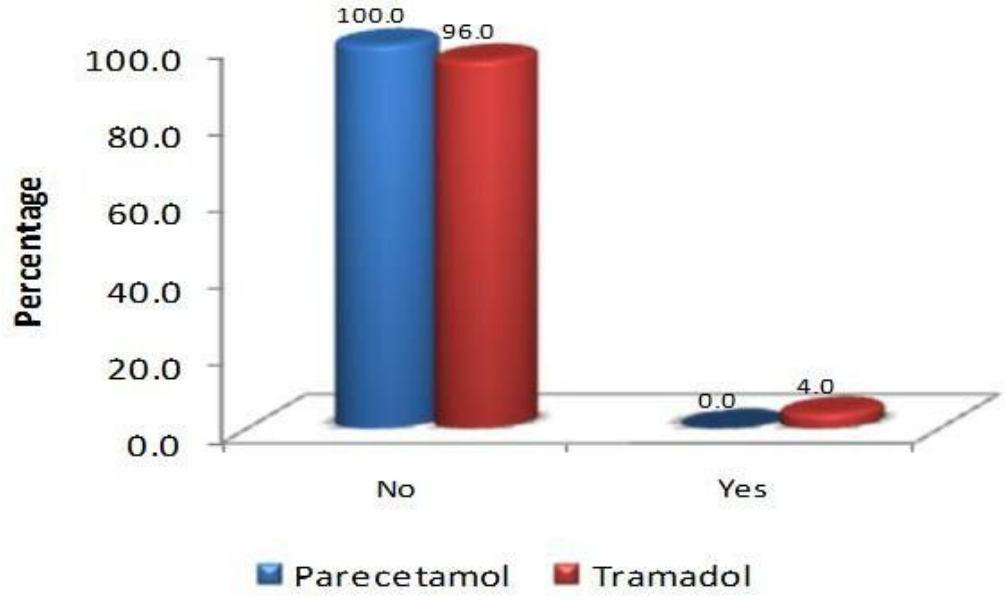

Figure 1. Comparison of Repeat Dose Based on Drugs

Time	Mean ± SD		Z#	p
	Paracetamol	Tramadol		
0 min	5.7 ± 1.1	5.6 ± 1	0.53	0.596
15 min	4.5 ± 1	5.3 ± 1	3.82**	0.000
1 hr.	3.9 ± 1.1	5.3 ± 1.4	5.18**	0.000

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2 hrs.	4.8 ± 1.3	6.2 ± 1.2	4.41**	0.000
3 hrs.	6.2 ± 1.3	7.2 ± 1.1	3.1**	0.002
4 hrs.	7.2 ± 0.8	7.9 ± 1.2	2.34*	0.019
# Mann-Whitney U Test **: - Significant at 0.01 level				
Table 3: Comparison of Pain Score at Different Interval between Drugs				

Drugs	**Mean**	**SD**	**N**	**t**	**p**
Paracetamol	3.0	1.1	39	5.61**	0.000
Tramadol	4.9	1.8	29		
****: - Significant at 0.01 level.**					
Table 4: Comparison of Duration of Labor between Drugs					

Labor duration showing marked variation between groups with a mean duration of 3 hours in the paracetamol group compared to 4.9 hours in the tramadol group.

Outcome	**Paracetamol**		**Tramadol**		χ^2	**p**
	Count	**Percentage**	**Count**	**Percentage**		
Normal Delivery	39	78.0	29	58.0	4.6*	0.032
Caesarean Section	11	22.0	21	42.0		
Table 5: Comparison of Pregnancy Outcome Based on Drugs						

The rate of caesarean section was significantly higher in the tramadol group [42%] as compared to the paracetamol group [22%] with a significant p-value = 0.032 by the chi-square test.

Adverse Effect on Baby	**Paracetamol**		**Tramadol**		χ^2	**p**
	Count	**Percentage**	**Count**	**Percentage**		
Nil	50	100.0	41	82.0	9.89**	0.002
NICU	0	0.0	9	18.0		
****: - Significant at 0.01 level**						
Table 6: Comparison of Adverse Effect on Baby based on Drugs						

The rate of NICU admission was higher in the tramadol group [18%] as compared to nil cases in the paracetamol group with a statistically significant p-value of 0.002 by the chi-square test.

Adverse Effect on Mothers	**Paracetamol**		**Tramadol**		χ^2	**p**
	Count	**Percentage**	**Count**	**Percentage**		
Nil	50	100.0	21	42.0	40.85**	0.000
Sedation	0	0.0	29	58.0	40.85**	0.000
Vomiting	0	0.0	25	50.0	33.33**	0.000
****: - Significant at 0.01 level**						
Table 7: Comparison of Adverse Effect of Mothers Based on Drugs						

APGAR	χ^2	**'p'**

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1 min	8.31*	0.016
5 mins	17.46**	0.000
: - Significant at 0.05 level *: - Significant at 0.01 level***		
Table 8: Comparison of APGAR at 1 Minute Based on Drugs		

100% of mothers in the paracetamol group reporting no adverse effects at all compared to the tramadol group [42%]. Sedation and vomiting being the reported statistically significant adverse effects in the tramadol group with p-value = 0.000 by the chi-square test.

DISCUSSION

Given that labor is typically regarded as an unpleasant experience, analgesia is frequently necessary. The average labor pain scores for primigravid and multigravid women were higher than those for sciatic, dental, or bone fracture pain, according to a study comparing various painful medical conditions.[9] A left shift in the mother's oxyhemoglobin dissociation curve and severe respiratory alkalosis can ensue from labor pain, which causes a considerable increase in minute ventilation and oxygen consumption during contractions, reducing oxygen transfer to the baby.[10]

A total of 100 full-term antenatals were enrolled in this study. 50 were randomly assigned to paracetamol group and 50 to tramadol group. All women received allocated interventions; parameters were assessed and were analysed according to group assignment. There was no significant variation between both groups with respect to age, BMI, and gravidity. Moreover, the baseline VAS pain scores at 0 minutes were also comparable between both groups.

VAS Score at 15 Minutes of Drug Administration

After 15 minutes of intravenous paracetamol administration, 8 women [16%] had mild pain, 41 women [82%] had moderate pain, and 1 woman [2%] had severe pain. In the tramadol group, one woman [2%] had mild pain, 45 women [90%] had moderate pain, and 4 women [8 %] had severe pain after 15 minutes of drug administration. This was **statistically significant** with a **p-value of 0.000** by the Mann-Whitney U test. In the study to compare the analgesic efficacy of intravenous paracetamol versus placebo in labor analgesia by Maeboud, significantly lower VAS scores were recorded in the paracetamol group at 15 minutes and 30 minutes after drug administration.[11]

VAS Score at 1 Hour of Drug Administration

After 1 hour of intravenous paracetamol administration, 22 women [44%] had mild pain, 26 women [52%] had moderate pain, and 2 women [4%] had severe pain [**mean score - 3.9 ± 1.1**]. In the tramadol group, 4 women [8.2%] had mild pain, 39 women [79.6%] had moderate pain, and 2 women [4%] had severe pain after 1 hour of intravenous drug administration [**mean score: 5.3 ± 1.4**]. This was **statistically significant** with a significantly higher VAS score in the tramadol group with a **p-value = 0.000** by the Mann-Whitney U test.

VAS Score at 2 Hours of Drug Administration

6 women [14.6%] reported mild pain, 30 women [73.2%] had moderate pain, and 5 women [12.2%] had severe pain in the paracetamol group after 2 hours of intravenous drug administration [**mean score 4.8 ± 1.3**]. Comparing this with the tramadol group, women reported only moderate and severe pain with 24 women [54.5 %] belonging to the former group and 20 women [45.5%] to the latter group [**mean score 6.2 ± 1.2**]. This was **statistically significant,** with lower VAS scores

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being reported at 2 hours in the paracetamol group as compared to the tramadol group, with a **p-value = 0.000** by the Mann-Whitney U test. In the study by Makkar et al.,[12] comparing the efficacy of IV paracetamol with IM tramadol, both groups showed comparable VAS scores at all times of observation. Lower mean VAS scores were reported in both groups till 120 minutes only.

VAS Score at 3 Hours of Drug Administration

At 3 hours after drug administration, none of the patients in both groups had mild pain. In the paracetamol group, 19 women [61.3%] had moderate pain while only 12 women [38.7%] reported severe pain **[mean score 6.2±1.3].** In the tramadol group, 9 women [25.7%] had moderate pain while 26 women [74.3%] had severe pain **[mean score 7.2±1.1]**. This was **statistically significant,** with mean VAS scores being lower in the paracetamol group with a **p-value of 0.002** by the Mann-Whitney U test.

VAS Score at 4 Hours of Drug Administration

At 4 hours after drug administration, none of the patients reported mild pain. In the paracetamol group, 3 women [18.8%] had moderate pain while 13 women [81.3%] had severe pain **[mean score 7.2 ± 0.8].** In the tramadol group, single woman [4.5 %] had moderate pain while the majority [21 women (95.5%)] had severe pain [**mean score - 7.9 ± 1.2**]. This was **statistically significant** with a **p-value of 0.019** by the Mann-Whitney U test. In the study by Abdollahi et al, IV paracetamol was compared with IM pethidine in 80 primigravid, full-term antenatals, and the VAS score was assessed only once at the end of delivery.[13] In the study, they had concluded that the average VAS score was higher in the pethidine group [9.6] vs. the paracetamol group [8.3]. In the study conducted by Elbohoty et al,[14] there was significant comparable pain reduction in both the pethidine and paracetamol groups at 15 minutes, 1 hour, and 2 hours [p value < 0.001]. The reduction in pain was significantly greater in the pethidine group only at 15 minutes (p = 0.004).

In the randomized comparative study by Ekweani et al.,[15] comparing IM pentazocine with IM acetaminophen, the pain relief produced by intramuscular acetaminophen was comparable with that produced by pentazocine from the second hour onwards after administration on the visual analogue scale. Pentazocine acts quicker than acetaminophen. However, once acetaminophen starts to act, it would produce analgesia comparable to pentazocine.

Our study's results indicate that the paracetamol group significantly reduced their pain scores across all VAS evaluation hours. This could be explained by the fact that tramadol has an onset within 10 minutes and an effect that lasts for 2-3 hours, but paracetamol has a peak analgesic effect at 1 hour and lasts for 4-6 hours. Concerns regarding tramadol's analgesic impact have also existed in the past since it is believed that its apparent analgesic efficacy may be attributable, at least in part, to its sleepy effect rather than a real decrease in perceived pain.

Requirement of Repeat Dose of Drugs

This parameter was evaluated to assess the efficacy of the drugs given. After 4 hours of drug administration, repeat dose requirements and willingness for it were sought from the patient. None of the subjects in the paracetamol group requested a repeat dose, while 2 women requested a repeat dose in the tramadol group. However, it was **statistically insignificant** with a p-value of 0.153 by the chi-square test.

Duration of Labor

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The duration of labor was compared between two groups. It was calculated from the onset of active labor [>3 cm dilatation, >60% effacement, and more than 3 contractions lasting >40 seconds in 10 minutes] till the birth of the baby. The mean duration of labor in the paracetamol group was **3 hours** as against the tramadol group, which was **4.9 hours**. Thus the paracetamol group had **a statistically significant** reduction in duration of labor as compared to the tramadol group with **p value = 0.000.** Fletcher[16] et al., in their small pilot study comparing the analgesic efficacy of IV paracetamol with opiates, also concluded that paracetamol reduced the duration of the second stage of labor. In their study, the paracetamol group had a mean duration of the second stage of labor of less than 60 minutes in 59% of cases as against the control group [38%]. In a randomized prospective double-blind study by Makkar et al,[17] to compare the analgesic efficacy of intramuscular tramadol with intravenous paracetamol, the duration of labor was significantly reduced in the paracetamol group [4 hours] as against the tramadol group [5.9 hours] with a p-value of 0.003.

The contradicting study is the one by Suguna Shobharani et al.,[18] which compared the analgesic efficacy of tramadol in primi- and multi-parous women. Here, they concluded that tramadol significantly reduced the duration of labor in both groups, more in multipara. Another study by Khooshideh et al.,[19] comparing the efficacy of 75 mg IM pethidine with 100 mg IM tramadol also concluded that tramadol significantly reduced the duration of labor. As per our study, there was a statistically significant reduction in the duration of labor in the paracetamol group as compared to the tramadol group. One likely explanation for this could be that tramadol produces drowsiness, which reduces laboring women's mobility and may prolong the labor. Additionally, these women may have longer labors due to poorer pain alleviation than the paracetamol group. Since a shorter labor period has several potential advantages and improves maternal and perinatal outcomes, more research is needed to fully understand how intravenous paracetamol affects labor duration.

Normal Delivery versus Caesarean Section

The outcome of pregnancy in both groups was studied. It was found that the rate of normal delivery in the paracetamol versus tramadol group was 78% to 58%. The percentage of cases that went in for caesarean section in the paracetamol group was significantly less [22%] as against the tramadol group [42%]. This difference was **statistically significant** at a **p-value of 0.032** by the chi-square test [λ 2 = 4.6, significant at the 0.05 level]. This finding is against that proposed by Suguna Shobharani et al.,[18] where they concluded that tramadol significantly reduced the rate of LSCS deliveries.

Rate of NICU Admission in Babies

None of the babies in the paracetamol group required NICU admission as compared to 18% of the babies in the tramadol group. This was found to be **statistically significant** with a **p-value = 0.002** by chi-square test. This might be due to adverse effects of tramadol, which included neonatal respiratory depression. This was in par with the findings by Fletcher et al., in which none of the babies in the paracetamol group required NICU admission as compared to the opioid group.[16]

Maternal Adverse Effects Based on Drugs

None of the patients in the paracetamol group reported any adverse effects. This was compared with the tramadol group, which reported 58% of cases with sedation and 50% with vomiting. This was **statistically significant** with a **p-value = 0.000** by the chi-square test. This was in par with the study conducted by Maeboud et al.,[20] comparing intravenous paracetamol vs. intravenous

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pethidine in 102 low-risk primiparous women, where none of the subjects in the paracetamol group had reported any adverse effects while the pethidine group reported 64% adverse effects in the form of sedation, nausea, and vomiting. In the study by Ekweani et al.,[21] comparing the efficacy of IM acetaminophen with IM pentazocine, they concluded that patients who received pentazocine were thrice more likely to develop vomiting than those who received acetaminophen. Also, patients who received pentazocine were six times more likely than those who received acetaminophen to be dizzy or sedated.

CONCLUSION

1 g intravenous paracetamol is a significantly better analgesic than 50 mg intravenous tramadol in providing intrapartum analgesia, as concluded from the assessment of VAS scores at 15 minutes, 1 hour, 2 hours, 3 hours, and 4 hours of drug administration. Paracetamol insignificantly reduced the requirement of repeat doses of analgesic as compared to tramadol. It also caused a statistically significant reduction in duration of labor as compared to tramadol. Tramadol caused significantly higher maternal adverse effects compared to the paracetamol group. The rate of normal delivery versus Caesarean section was significantly higher in the paracetamol group as compared to the tramadol group. The indication for Caesarean section showed statistically insignificant variation between paracetamol and tramadol groups. The neonatal APGAR scores showed significant reduction in the tramadol group as compared to the paracetamol group. The rate of NICU admission in babies in the tramadol group was significantly higher as compared to the paracetamol group.

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