

# A study of intravenous infusion of Paracetamol versus intramuscular Tramadol for labour analgesia with respect to VAPS score at a rural tertiary health care centre

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## Abstract

**Background:** The pain of child birth is the most severe pain, most women will undergo in their lifetime and any measures taken to alleviate would enable them to go through this difficult period with confidence and comfort. **Objective:** To study the effects of intravenous infusion of Paracetamol versus intramuscular Tramadol for labor analgesia with respect to VAPS score at a rural tertiary health care centre. **Methodology:** This was a prospective, randomized clinical and comparative observational study done at the Department of Obstetrics and Gynecology, P.E.S. Institute of Medical Sciences and Research, Kuppam and approved by the Institutional Human Ethics Committee (IHEC). 100 parturients who presented in spontaneous labour were enrolled in the study after a written informed consent. The data was analyzed by un-paired t-test and chi-square test and calculated by the statistical software namely SPSS 18.0 and R environment version 3.2.2 were used for the analysis of the data. **Results:** The study group comprised 100 subjects including primigravid and multiparous parturients. The mean age of patients in the Paracetamol group was 23.82± 2.04 and in the Tramadol group was 24.48±2.40 years which were comparable with each other (p>0.05) Gestational age of the patient varied between 37-41 weeks in the Paracetamol and Tramadol groups with mean gestational age of 39.38± 0.77 and 39.26± 0.77 weeks respectively and this was comparable (p>0.05). Visual Analogue Pain Scale (VAPS) 1 hr after the drug administration in the study groups (p value 0.006) was statistically significant. Pain was reduced significantly after 1hr of drug administration in the Paracetamol group than in the Tramadol group. Visual Analogue Pain Scale (VAPS) 3hr after the drug administration in study groups (p value 0.282), was not statistically significant. **Conclusion:** It was concluded from our study that the pain after 1 hour of Paracetamol administration reduced significantly by VAPS hence injectable Paracetamol could be preferred over Injectable Tramadol in labour analgesia.

**Key Words:** Labor Analgesia

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## INTRODUCTION

The pain of child birth is the most severe pain, most women will undergo in their lifetimes. Labor results in

severe pain for many women. There is no other circumstance where it is considered acceptable for a person to experience untreated severe pain, amenable to safe intervention, while under a physician's care. In the absence of a medical contraindication, maternal request is a sufficient medical indication for pain relief during labor<sup>1</sup> Women in pain don't need an indication for pain relief in labor. The delivery of the infant into the arms of a conscious and pain-free mother is one of the most exciting and rewarding moments in medicine<sup>2</sup>. Labor may be the most painful experience many women ever encounter. The experience is different for each woman and the different methods chosen to relieve pain depend upon the techniques available locally and the

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personal choice of the individual.<sup>3</sup> Pain relief in labor has always been surrounded with myths and controversies. Hence, providing effective and safe analgesia during labor has remained an ongoing challenge.

Historically, the era of obstetric anaesthesia began with James Young Simpson, Professor of Midwifery at the University of Edinburgh, when he administered ether to a woman with a deformed pelvis during childbirth. His concept of etherization of labor was strongly condemned by critics!

In the evidence-based management of labor pain, numerous strategies, both pharmacologic and non-pharmacologic, have been used in the treatment of labor pain.<sup>4</sup> Labor pain affects maternal psychology and the course of labor causing apprehension, anxiety and stress. Pain during the first stage of labor originates predominantly due to cervical dilatation and uterine muscle wall ischemia leading to lactate accumulation. During the late first stage and second stage of labor, the vagina and perineum form additional sources of pain. The associated increase in sympathetic activity leads to increased oxygen consumption, respiratory alkalosis, and metabolic acidosis which could lead to decreased oxygen being transferred to the fetus. Thus, pain relief during labor is expected to reduce maternal stress and improve the maternal and perinatal outcome.

Obstetric analgesia and anesthesia has now evolved from a vague possibility to reality. The non-pharmacological techniques of analgesia include emotional support, relaxed birth environment, psycho-somatic preparation, yoga, acupuncture, and transcutaneous electrical nerve stimulation (TENS). The commonly used and more effective are pharmacological techniques which include opioids like pethidine and tramadol, though regional analgesia is the gold standard nowadays and routinely used in modern obstetric anesthesia in developed countries.<sup>5</sup> The newer advances like combined spinal epidurals, low dose epidurals, patient controlled intravenous, inhalational, and epidural analgesia have revolutionized obstetric pain relief<sup>6</sup>. But most of modern obstetric analgesia practices involve participation of expert anesthesiologists, costly equipment, and continuous monitoring facilities which unfortunately cannot be available in routine obstetric practice in the developing countries where a majority of obstetric services are in the hands of midwives, trained nurses, and non-specialist doctors. In such situations, a method with minimum technicality is desired. Paracetamol, the mode of analgesic action of which has still not been fully elucidated but probably is a centrally acting drug which inhibits prostaglandin synthesis, has recently been made available as intravenous preparation. Various studies have proved intravenous paracetamol as effective analgesic

agent which is safe, effective, inexpensive, and requires no special monitoring<sup>7,8,9</sup>. However, there are no significant trials regarding the analgesic effect of paracetamol on labor pain in women. If proved to be an effective analgesic agent in labor, paracetamol being inexpensive and simple to administer could be a boon for obstetric analgesia in developing countries. Only a few studies have documented the safety and efficacy of intravenous paracetamol as a labor analgesic<sup>5,10</sup>. Tramadol hydrochloride is a centrally acting opioid analgesic; intramuscular tramadol hydrochloride is commonly used in labor analgesia in developing countries as it is inexpensive, no special monitoring is required and it has been widely studied and proven for its safety and efficacy in labor analgesia<sup>11,12,13</sup>.

## METHODOLOGY

This was a prospective randomized, clinical, comparative observational study and this convenient sampling study protocol was developed at Department of Obstetrics and Gynecology, P.E.S. Institute of Medical Sciences and Research, Kuppam and approved by the Institutional Human Ethics Committee (IHEC). A hundred parturients who presented in spontaneous labour were enrolled in the study after a written informed consent was obtained.

### Inclusion criteria –

1. Primigravid and multiparous low risk parturients
2. Age between 18-35 years
3. Spontaneous onset of labour at term (37-42 weeks of gestation)
4. First stage of labour with cervical dilatation of 3-6cm
5. Single viable foetus
6. Cephalic presentation

### Exclusion criteria -

1. Clinical evidence of cephalo-pelvic disproportion,
2. Malpresentation,
3. Multiple pregnancies,
4. Previously scarred uterus
5. Preterm labour,
6. Induced labour,
7. Antepartum haemorrhage,
8. Pregnancy induced hypertension,
9. History of drug allergy to paracetamol and tramadol
10. Previous history of liver disease

Parturients(n=100) who desired labour analgesia were randomly allocated into the study groups namely Paracetamol (n=50) and Tramadol (n= 50 ) groups. In women included in the study, a detailed history, general

physical examination, obstetric examination including vaginal examination where indicated, was done and all the required investigations carried out. Pain intensity was recorded by VISUAL ANALOGUE PAIN SCALE(VAPS) half an hour before administration of study drugs and after 1 hour and 3 hours of study drugs administration and then the same procedure was repeated after 3hrs if necessary. The VAPS score was divided into four parts: no pain (VAPS score 0), mild pain (VAPS

score 0.1-3.9), moderate pain (VAPS score 4-6.9) and severe pain (VAPS score 7-10). The data was analyzed by un-paired t-test and chi-square test, and calculated by statistical software namely SPSS 18.0 and R environment version 3.2.2 ,which were used for the analysis of the data.

## RESULTS

**Table 1:** Age distribution in the two participant groups

Age in years	Paracetamol(%)		Tramadol (%)		TOTAL(%)	
18-25 Years	39	78%	32	32%	71	(71%)
26-35Years	11	22%	18	36%	29	(29%)
TOTAL	50	100%	50	100%	100	(100)
Mean±SD	23.82± 2.04		24.48±2.40		24.15±2.24	

The study group comprised 100 subjects including primigravid and multiparous parturients. The mean age of patients in Paracetamol group was 23.82± 2.04 and in the Tramadol group was 24.48±2.40 years which was comparable with each other (p>0.05)

**Table 2:** Mean gestational age (weeks ) in the two participant groups

Gestation Age(weeks )	INJ. PARACETAMOL	INJ. TRAMADOL	TOTAL
37-39 weeks	25(50%)	30 (60%)	55 (55%)
39-40 weeks	24 (48%)	19 (38%)	43 (43%)
40+weeks	1 (2%)	1(2%)	2 (2%)
Total	50 (100%)	50 (100%)	100 (100%)
Mean ±SD	39.38 ± 0.77	39.26 ± 0.77	39.32±0.77

Gestational ages of the patients varied between 37-41 weeks in the Paracetamol and Tramadol groups with mean gestational age of 39.38± 0.77 and 39.26± 0.77 weeks respectively and with mean gestational age of 39.32±0.77 weeks. This was comparable (p>0.05)

**Table 3:** Number of doses of medicine given in the study groups

No of doses repeated	Paracetamol	Tramadol	Total
Single dose	49 ( 98%)	47( 94%)	96 (96%)
Two doses	01(02%)	03(0 6%)	04 (04%)
<b>Total</b>	<b>50 (100%)</b>	<b>50 (100%)</b>	<b>100 (100%)</b>

Pearson chi2(1)= 1.0417 , pr = 0.307

The no. of doses of medicine required in both the groups was comparable (X2=1.0417,p>0.05)

**Table 4:** Visual analogue pain scale (VAPS) 1 hr after the drug administration in the study groups

VAPS 1 hr after drug Administration	Paracetamol	Tramadol	Total
4	4( 8%)	2( 4%)	6(6%)
5	27(54%)	14( 28%)	41(41%)
6	19(38%)	28(56%)	47(47%)
7	0(0%)	6( 12%)	6(6%)
<b>Total</b>	<b>50(100%)</b>	<b>50 (100%)</b>	<b>100(100%)</b>

Pearson chi2 (1) = 12.5120, pr = 0.006

Visual analogue pain scale (VAPS) 1 hr after the drug administration in study group p value was 0.006 ;it was statistically significant. Pain was reduced significantly after 1hr of drug administration in the Paracetamol group than in Tramadol group.

**Table 5:** Visual analogue pain scale (VAPS) 3 hr after the drug administration in the study groups

VAPS 3 hr after drug Administration	Paracetamol	Tramadol	Total
4	32( 82.05%)	15( 68.18%)	47(77.05%)
5	5(12.82%)	4( 18 .18%)	9(14.75%)
6	1(2.56%)	3(13.64%)	4(6.56%)
7	1(2.56%)	0( 0%)	1(1.64%)
<b>Total</b>	<b>39(100%)</b>	<b>22 (100%)</b>	<b>61(100%)</b>

Visual analogue pain scale (VAPS) 3hr after the drug administration in study group, p value was 0.282; it was statistically not significant.

## DISCUSSION

Childbirth is an important experience in a woman's life;<sup>17</sup> nevertheless, labor pain was considered to be one of the most intense and stressful experiences,<sup>18</sup> being compared in intensity to severe cancer pain or pain from the amputation of a digit.<sup>18,19</sup> Adequate analgesia during labor has a positive influence on the course of labor,<sup>19</sup> and most women who deliver in modern obstetric units request some form of pharmacological or non-pharmacological pain relief.<sup>20</sup> In our study the study groups comprising 100 subjects including primigravid and multiparous parturients, the mean age of patients in Paracetamol group was 23.82±2.04 and in the Tramadol group was 24.48±2.40 years which was comparable with each other (p>0.05). Gestational age of the patients varied between 37-41 weeks in the Paracetamol and Tramadol groups with mean gestational age of 39.38± 0.77 and 39.26± 0.77 weeks respectively-this was comparable (p>0.05) The number of doses of medicine required in both the groups was comparable (X<sup>2</sup>=1.0417,P>0.05). Visual analogue pain scale (VAPS) 1 hr after the drug administration in study group had a 'p' value of 0.006; which was statistically significant. Pain was reduced significantly after 1hr of drug administration in the Paracetamol group as compared to the Tramadol group. Visual analogue pain scale (VAPS) 3 hours after the drug administration in study groups, (p value 0.282) was statistically not significant. These findings are similar to Hema Mohan<sup>21</sup> *et al* and Bishnu Prasad<sup>22</sup> *Das et al*.

## CONCLUSION

It can be concluded from our study that the pain after 1 hour of Paracetamol administration reduced significantly by VAPS as compared with Tramadol and hence injectable Paracetamol should be preferred over Injectable Tramadol as the latter is also known to have more complications. However more studies need to be undertaken for its wider use in labour analgesia .

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