Original Article

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Comparison of Intravenous Paracetamol Infusion Versus Intramuscular Tramadol as an Intrapartum Analgesic

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Author`s Contribution

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ABSTRACT

Objective: To compare the mean intrapartum pain score between intravenous paracetamol infusion and intramuscular tramadol.

Methodology: This randomized controlled trial was conducted at the Department of Obstetrics and Gynecology, Indus Hospital, Muzaffargarh, from August 2023 to February 2024, included women with full-term pregnancy, aged 20–40 years, carrying a single fetus, and having a spontaneous onset of labor in the active phase. Participants were equally divided into two groups: Group A received intravenous paracetamol, while Group B received intramuscular tramadol. Pain scores were recorded before drug administration and at 1 and 3 hours post-administration. The mode of delivery and duration of labor were also documented.

Results: The mean age of the participants was 27.7 ± 4.2 years. The mean duration of labor was significantly shorter in the paracetamol group (4.6 ± 0.8 hours) compared to the tramadol group (5.9 ± 0.8 hours) (p = 0.001). Furthermore, the mean pain score at three hours after treatment was significantly lower in the paracetamol group compared to the tramadol group (mean VAS = 6.8 ± 0.8 vs. 7.8 ± 0.7, respectively) (p = 0.001).

Conclusion: Intravenous paracetamol was found to be more effective in providing labor analgesia and in reducing the duration of labor compared to intramuscular tramadol. Additionally, it is an easy, affordable, and practical option for use in low-resource settings where access to advanced healthcare facilities is limited.

Keywords: Labor, Pain, Tramadol, Acetaminophen.

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Introduction

The labor is a natural process biologically considered by regular, the painful uterine contractions that lead to decreased the flow of blood to muscles of uterus, continuing thinning and opening of the cervix, extending of the perineal tissues and the vaginal canal, and the pressure on structure of the pelvis.[1] It is considered as the one of the most severe forms of the pain faced by women during their years of reproduction and is often go together with emotionally negative responses like fear, anxiety, and a decreased sense of safety, which may influence the patients to prefer the delivery by cesarean section.[1,2] Both the expectation and actual experience regarding pain of the labor can be distressing, specifically for the primiparous women (first-time mother), who usually experience greater level of fear and anxiety.

However, the related elevation in sympathetic activity results in respiratory alkalosis, metabolic acidosis, and increased oxygen demand, all of which may reduce the amount of oxygen delivered to the developing fetus.[3]

However the effective management of labor pain is therefore very important not only for comfort of the mother but also for decreasing the neuroendocrine responses induced by stress, that can adversely influence

the progression of labor and feto-maternal outcomes.[4] In the limited resource locations, the awareness and intrapartum analgesia uses remain very inadequate.[5] In underserved areas of Pakistan mostly maternity care is served by lady health workers, the nursing staff, and general medical practitioners due to the gaps in the system of healthcare.[5] Additionally, several obstetric analgesic techniques need costly equipment, proper monitoring, and the availability of trained anesthesiologists, resources that are mainly not available.[5,6] Usually, systemic opioids have been utilized for the labor analgesia in limited resources regions due to easily of administration and lack of requirement of specialized equipment. Though the usage of opioid is related to with many maternal side effects like nausea and vomiting and the possible neonatal effects like respiratory depression,[7] which may decrease the benefits.

The Tramadol, a centrally acting analgesic similarly to pethidine with weak μ-opioid receptor,[8] agonism and inhibition of serotonin and norepinephrine reuptake, has been extensively used in several clinical situations as a substitute to stronger opioids due to its satisfactory profile of side effect and less intensive monitoring requirement. In the field of obstetric, the intramuscular tramadol has been used as an analgesia in labor in developing nations because it is non-expensive, administration route is simple, and usually safe for both fetus and the mothers. On the other hand, concerns remain about its analgesic effectiveness relation to other painkiller agents, besides the occurrence of side effects for mother like nausea and vomiting.[7]

On the other hand, acetaminophen is a non-opioid analgesic agent with both mechanisms of action of central and peripheral.[9] Although its exact mechanism remains incompletely known, but paracetamol is believed to inhibit cyclo-oxygenase (COX) enzymes in the CNS, thereby reducing prostaglandin synthesis and modulating nociceptive pathways.[9,10] It may also enhance descending serotonergic inhibitory pathways and interact with endocannabinoid systems, contributing to its analgesic and antipyretic effects with minimal anti-inflammatory action. Intravenous administration of paracetamol ensures rapid systemic availability and has been increasingly studied for acute pain management in surgical and obstetric settings. Compared to opioids, paracetamol offers a potentially safer profile with fewer side effects and no requirement for intense maternal or fetal monitoring.[8] Though, the evidence on analgesic effectiveness of both drugs and maternal-fetal outcomes remains inconsistent and limited at local level. Hence this study has been planned to compare intrapartum analgesic effect of IV paracetamol versus IM tramadol in our local setting to reconfirm the more effective analgesic agent. After proving the effectiveness as a more effective analgesic agent in labor, it can be incorporated into local routine practice to provide obstetric analgesia, especially in limited resources regions.

Methodology

A Randomized Controlled Trial was conducted at department of obstetrics and gynecology, Recep Tayyip Erdogan Hospital, during six-month duration (from 11th August 2023 to 11th February 2024). The sample size of 70 patients (35 in each group) was calculated through Open-Epi software using formula for mean difference, where, mean pain score at 3-hours in IV paracetamol group = 4.97±0.64 and mean pain score at 3-hours in IM tramadol group = 5.4± 0.63, with power of the study = 80% and confidence level = 95%. The non-probability consecutive sampling technique was used. According to the inclusion criteria all the primigravida women with full-term pregnancy, age range from 20 to 40 years, single fetus, with vertex presentation and with spontaneous onset of labor in active phase of labor were included. However, the women with history of underlying chronic medical conditions, scarred uterus, clinical evidence of cephalo-pelvic disproportion, and history of allergy to any opioid or hypersensitivity to the drugs were excluded. This study was conducted after permission from ethical review committee. After informed consent and explanation of purpose of study, baseline and clinical information was noted. The participants were assigned to group A and B through lottery method where each participant picked a sealed opaque envelope containing the slip marked with either group A or group B. The women in group A were given paracetamol 100 ml intravenous infusion containing 1,000 mg of paracetamol single dose over 15 min, and all the women in the group B were given tramadol hydrochloride 100 mg intramuscular single dose in upper & outer quadrant of gluteal region with a 2- ml syringe.

Pain intensity before giving drug was recorded using VAS. Labor was monitored using a partogram. Measurement of pain relief was done with VAS before, after 1 and 3 h of drug administration. Mode of delivery and duration of labor were recorded in all participants. All the data was recorded on proforma. Subsequently the SPSS version 23 was used for data analysis. The pain scores between the two groups were compared by

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independent sample test taking p-value ≤ 0.05 as significant statistically. Moreover, the data was stratified based on effect modifiers (age, gestational age and BMI) and post-stratification independent sample test was used and p-value ≤0.05 was considered as statistically significant.

Results

The mean age of the women was 27.7 ± 4.2 years. Most of women had primary-level education (45.7%) and only 4.3% had graduate-level or higher education while 15.7% were illiterate. Majority of the women were housewives (85.7%), belonged to rural areas (68.6%), and lived in extended family systems (74.3%). Around 85.7% women delivered via NVD and remaining 14.3% underwent cesarean section. Additionally, the duration of labor was significantly shorter (4.6 ± 0.8 hours) in paracetamol group compared to tramadol group (5.9 ± 0.8 hours). Table I

The average pain score (VAS) enrollment was higher and comparable between the paracetamol and tramadol groups (8.8 ± 0.9 versus 8.6 ± 0.8) respectively, which was slightly decreased after one hour of administration in both groups (7.2 ± 0.9 vas 7.5 ± 0.6) without significant difference. However, it was noted with significant reduction in paracetamol group 4.2 ± 0.8 compared to the tramadol group 6.1 ± 0.7 (p=0.001). Table II

Table II: Pain Score in women presenting in active phase of labour. (n=70)

Characteristics	Overall (N=70)	Paracetamol Group (n=35)	Tramadol Group (n=35)	p-value*
VAS on enrolment	8.7 ± 0.9	8.8 ± 0.9	8.6 ± 0.8	0.423
VAS after 1-hour	8.2 ± 0.8	7.2 ± 0.9	7.5 ± 0.6	0.883
VAS after 3-hour	7.3 ± 0.9	3.2 ± 0.8	4.1 ± 0.7	0.001

**Independent sample t-test*

Overall mean pain score at 1 hour and at 3rd hour was found statistically insignificant according age of women, gestational age and BMI in both groups separately (p>0.05), as shown in Table III and IV.

Discussion

The management of intrapartum pain remains one of the most critical and widely discussed aspects of obstetric

Table I: Characteristics of women in active phase of labour. (n=70)

Characteristics	Overall (n=70)	Paracetamol Group (n=35)	Tramadol Group (n=35)	p-value*
Age (years)	27.7 ± 4.2	28.0 ± 4.1	27.5 ± 4.3	0.590
BMI (Kg/m^2)	23.01±2.66	23.24±2.97	22.52±2.03	0.241
Educational Status				
Illiterate	11 (15.7)	8 (72.7)	3 (27.3)	
Primary	32 (45.7)	15 (46.9)	17 (53.1)	
Secondary	15 (21.4)	9 (60.0)	6 (40.0)	0.152
Higher Secondary	9 (12.9)	3 (33.3)	6 (66.7)	
Graduate and above	3 (4.3)	0 (0.0)	3 (100)	
Occupation				
Employed	10 (14.3)	5 (50)	5 (50)	1.00
Housewife	60 (85.7)	30 (50)	30 (50)	
Residence				
Rural	48 (68.6)	26 (54.2)	22 (45.8)	0.303
Urban	22 (31.4)	9 (40.9)	13 (59.1)	
Family Type				
Nuclear	18 (25.7)	8 (44.4)	10 (55.6)	0.584
Extended	52 (74.3)	27 (51.9)	25 (48.1)	
Duration of labour	5.2 ± 1.0	4.6 ± 0.8	5.9 ± 0.8	0.001
Mode of delivery				
SVD	60 (85.7)	32 (53.3)	28 (46.7)	0.306
Cesarean section	10 (14.3)	3 (30)	7 (70)	

Table III: Effect of demographic characteristics on pain score at 1-hour and 3rd hour in tramadol group (n=35)

Variables		N	Pain score at one hour Mean	SD	p-value	Pain score at 3rd hour Mean	SD	p-value
Gestational age	37-38 weeks	12	7.250	0.96	0.061	5.17	1.46	0.115
	39-40 weeks	23	6.130	1.35		4.43	1.16	
Age groups	18-30 years	32	7.62	1.31	0.111	5.75	1.32	0.347
	31-40 years	03	6.333	1.15		4.00	1.00	
BMI kg/m^2	Normal (18.5-24.9)	30	7.50	1.35	0.042	5.45	1.438	0.116
	Overweight (25.29.9)	5	6.60	1.34		4.69	1.182	

Table IV: Effect of demographic characteristics on pain score at 1-hour and 3rd hour in paracetamol group. (n=35)

Variables		N	Pain score at one hour		p-value	Pain score at 3rd hour		p-value
			Mean	SD		Mean	SD	
Gestational age	37-38 weeks	19	6.263	1.5931	0.562	4.47	1.577	0.162
	39-40 weeks	16	5.938	1.6919		3.81	1.047	
Age groups	18-30 years	28	6.000	1.6555	0.413	4.04	1.401	0.251
	31-40 years	7	6.571	1.5119		3.71	1.254	
BMI kg/m²	Normal (18.5-24.9)	22	6.36	1.64	0.243	4.83	1.262	0.101
	Overweight (25.29.9)	13	5.69	1.54		3.80	1.304	

care. Intravenous paracetamol and intramuscular tramadol have both emerged as commonly used analgesic options during labor, each with distinct pharmacological properties, effectiveness, and potential adverse effects that require careful comparative evaluation. This study was conducted on 70 participants to compare the mean intrapartum pain scores between intravenous paracetamol infusion and intramuscular tramadol. The overall mean age of the participants was 27.7 ± 4.2 years, with a mean age of 28.0 ± 4.1 years in the paracetamol group and 27.5 ± 4.3 years in the tramadol group. These findings are consistent with those reported by Rehman A et al.[10] and Marwah M et al.[8].

Objectively in this study mean pain score was slightly decreased after one hour of administration in both groups (7.2 ± 0.9 vas 7.5 ± 0.6) without significant difference, while it was noted with significant reduction in paracetamol group 4.2 ± 0.8 compared to the tramadol group 6.1 ± 0.7 (p=0.001). In agreement with our findings Mushtaq N et al[8] conducted the study on 100 divided equally into two groups receiving either intravenous paracetamol or intramuscular tramadol, where paracetamol showed superior analgesic efficacy with significantly lower VAS scores at both 1 hour and 3 hours (4.44 versus 5.55 and 6.51 versus 6.96), p=0.001 respectively among with shorter first stage of labor (10.16 versus 11.44 hours) p=0.0), and the lower rate of maternal side effects in contrast to tramadol group (12% versus 24%) respectively, with statistical insignificance (p=0.118).

Our findings were further supported by Monisha N et al.[12], who enrolled 110 women into two equal groups and reported that intravenous paracetamol demonstrated superior analgesic efficacy compared to intramuscular tramadol at both 180 and 240 minutes, as evidenced by significantly lower mean VAS scores in the paracetamol group (4.97 ± 0.64 vs. 5.4 ± 0.63; p = 0.004) and (4.75 ± 0.78 vs. 5.36 ± 0.73; p = 0.011), respectively. In the parallel with our findings Lallar M et al[13] reported that the IV paracetamol proved to be a more effective labor analgesic, as evidenced by considerably lower rates of severe pain at the both assessment time points; at 1 hour, only 4% and 28% of women in the paracetamol group experienced horrible and distressing pain respectively, in contrast to 30% and 60% in the group of tramadol, while at 3rd hour assessment, 26% of women in the paracetamol group showed distressing pain and tramadol group continuously showed higher level of pain with 50% experiencing horrible pain and 36% distressing pain. In line with findings of this study Rawat S et al[14] demonstrated that the paracetamol group showed the significantly lower mean VAS scores in contrast to control group across all time points, with scores of (3.57±1.15 versus 8.52±0.82) at one hour, (3.3±1.39 versus 7.52±1.02) at 2nd hour, (3.51±1.31 versus 7.64±0.7) at third hour, and (3.81±1.47 versus 7.56±1.21) at 4th hour, with all differences reaching high statistical significance (p<0.001), proving that IV paracetamol provides significantly superior pain relief during the active phase of labor. On the other hand Das BP et al[15] demonstrated that the IV paracetamol is more effective intrapartum analgesic contrast to IM tramadol, offering superior pain relief, a shorter labor duration, and a more favorable maternal outcomes.

Few other studies also observed that the IV paracetamol represent a superior analgesic option over administration of tramadol and few other agents during the labor, in terms of pain relief efficacy and its correlation with a significantly lower incidence of side effects.[16-20]

Like few above studies this study also found significantly short duration of labor (4.6 ± 0.8 hours) in paracetamol group compared to tramadol group (5.9 ± 0.8 hours) P=0.001) and less adverse effects, which were further supported by the studies by Cobos Tobar JK et al[21], Priyadarshini P et al[21], and Anter ME et al[21]. Overall, numerous recent studies, including the present study, have consistently demonstrated that intravenous paracetamol provides superior intrapartum analgesia compared to other commonly used analgesics, with significantly lower pain scores across all stages of active labor, as well as a shorter duration of the first stage of labor. Paracetamol exerts its analgesic effects primarily through inhibition of central prostaglandin synthesis via cyclooxygenase enzyme pathways within the central

nervous system, thereby reducing the sensitization of pain receptors at the level of the spinal cord. Moreover, paracetamol is believed to modulate descending serotonergic inhibitory pain pathways and interact with endocannabinoid receptors, further enhancing its analgesic effect at both peripheral and central levels.

Conclusion

The findings of this study revealed that the IV paracetamol observed as a safe, effective, and well-tolerated intrapartum analgesic agent that provides superior pain relief in contrast to intramuscular tramadol, as evidenced by significantly lower pain score specifically at after 3-hour during the active phase of labor. It was also associated with significantly shorter duration of the first stage of labor and a considerably lower incidence of maternal side effects. However due to certain limitations of the study, further larger multicenter trials are encouraged to authorize these findings and establish standardized protocols for its routine use in obstetric practice.

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