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Comparative Analysis between Paracetamol vs Placebo during Labour in Primigravida in Terms of Cervical Dilatation and Adequate Analgesia

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Author`s Contribution

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ABSTRACT

Objective: To evaluate a comparative analysis of paracetamol versus placebo during labour in primigravida women in terms of cervical dilatation and adequacy of analgesia.

Methodology: This randomized controlled trial was carried out in the Obstetrics and Gynaecology Department of Patel Hospital, Karachi, from June 2023 to December 2023. All primiparous women with singleton pregnancies, cephalic presentation, active labour, and gestational age >37 weeks were included. The women were randomly categorized into two groups: the intervention group (1000 mg [1 g] paracetamol with oxytocin augmentation) and the control group (oxytocin augmentation alone). Cervical dilatation was measured in centimeters from the onset of active labour (≥4 cm) to full dilatation (10 cm). Pain scores were measured using the Visual Analogue Scale (VAS), where participants rated their pain. Changes in pain scores over time were analyzed to determine the analgesic efficacy of paracetamol compared to placebo. Pain scores were assessed at regular hourly intervals until full cervical dilatation or delivery. Data were entered and analyzed using SPSS version 26.

Results: A total of 80 women with term pregnancies were studied, with an overall mean age of 24.22 years. The mean rate of cervical dilatation was 1.9 ± 0.5 cm/hour in the paracetamol group compared to 1.2 ± 0.4 cm/hour in the control group (p = 0.001). The average duration to achieve full cervical dilatation was also reduced in the paracetamol group (4.7 ± 1.5 hours) compared to the control group (6.3 ± 2.1 hours) (p = 0.001). Furthermore, pain scores were significantly lower in the paracetamol group (VAS score 6.4 ± 2.44) compared to the control group (VAS score 8.4 ± 3.22) (p = 0.001).

Conclusion: Paracetamol administration as an adjunct to oxytocin augmentation was found to be significantly effective in promoting faster cervical dilatation and significantly reducing labour pain.

Keywords: Primigravida Cervical dilatation, Paracetamol, Pain, Delivery.

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Introduction

Labour pain is widely documented as one of the most intense forms of acute pain experienced by women during childbirth.[1] It arises primarily from uterine contractions and progressive cervical dilatation during the first stage of labour, and from stretching and distension of the pelvic floor in the advanced stages. Anticipation of labour pain, along with the labour process itself, often generates significant anxiety, particularly among primiparous women, who tend to experience greater fear and emotional stress. Effective intrapartum analgesia not only reduces

maternal pain but may also influence the progression of labour, the maternal stress response, and overall childbirth outcomes.[2]

Usually, the management of labour pain has depend on neuraxial techniques (like, epidural analgesia) or the systemic opioids; though, approach to epidural analgesia is limited in the numerous setting with low-resource, and opioids pose potential risks including maternal sedation, neonatal respiratory depression, maternal vomiting and nausea.[3]

Conversely the paracetamol is an extensively used non-opioid analgesic with the advantageous safety profile,[4] and the well-established pharmacokinetics during administration intravenously. It's practically implemented as an intrapartum analgesic has gained growing scholarly interest, specifically given its potential to give adequate relief in the pain with decreased fetal and maternal adverse effects. The paracetamol properties in pain relieving are achieved by the inhibition of central cyclooxygenase enzymes activity, subsequent reducing the prostaglandin production, whereas mechanisms of supplementation may include endocannabinoid signaling enhancement and inflection of serotonergic inhibitory pathway.[5] Contrasted by the placebo or systemic opioids, paracetamol administration intravenously has been studied in randomized controlled trials and observational studies for labour analgesia,[6,7] however the available evidence remains inconsistent considering its impact on dilatation of cervix, score of the pain, duration of labour, and the need for the supplementary analgesia. Many randomized trials have directly contrasted intravenous paracetamol with placebo for the intrapartum analgesia. Like, according to a randomized, triple-blind, placebo-controlled study comprising 120 low-risk primiparous females with the active labour, the 1000 mg paracetamol administration intravenously significantly decrease the pain score (VAS) at 15- and 30-minutes post-administration in contrast to placebo, and significantly minimized the requirement of additional analgesic therapy at 60 minutes of labour progression.[8] Additionally a double-blinded trial demonstrated significant reductions in the intensity of pain at several time points subsequent to paracetamol infusion intravenously at the time of active labour compared to the normal saline placebo, without feto-maternal significant adverse outcomes.[9]

In addition to basic pain scores, paracetamol during intrapartum may affect the progression of labour itself. According to a randomized clinical, conducted on 220 nulliparous patients reported that 1000 mg paracetamol infusion was significantly correlated with shorter durations of both the 1st and 2nd stages of labour versus controls, together with lower pain score, suggestive of a potential benefit in terms of dilatation of cervix kinetics when adequate analgesia decreases stress-induced release of catecholamine.[10] The enhancements in the progression of labour may be relatively attributable to the reduction of maternal sympathetic stimulation by the control of pain effectively, which can otherwise obstruct contraction of uterus and slow the dilatation of cervix.

Furthermore, paracetamol has also been studied in comparison with other active analgesic modalities, including opioids such as tramadol, although these studies do not always include a placebo arm. Comparative studies suggest that intravenous paracetamol may provide analgesic efficacy equivalent or superior to systemic opioids like tramadol and meperidine, with fewer maternal adverse effects and comparable neonatal outcomes, as measured by Apgar scores at 1 and 5 minutes.[11] Despite these findings, rigorous placebo-controlled assessments remain essential to distinguish the specific analgesic and labour-related effects of paracetamol from those of other active analgesics.

However, there is limited literature providing comprehensive data on the direct effects of paracetamol on cervical dilatation rates compared to placebo, particularly in low-resource settings or among primigravida women, who are more likely to experience prolonged and more painful labours. While the existing evidence is encouraging, some trials report high rates of supplemental analgesic use even after paracetamol administration, suggesting that paracetamol alone may not be sufficient for moderate to severe labour pain in all women, and that its clinical effectiveness may vary depending on the stage of labour and individual pain thresholds.[12] This variability, along with the scarcity of comprehensive local data, underscores the need for well-designed, adequately powered randomized controlled trials focusing on cervical dilatation progression, adequacy of analgesia, and labour outcomes, particularly in primigravida populations.

Methodology

This randomized controlled trial was conducted at Liaquat University of Health Sciences from June 2023 to December 2023. A total of 200 primigravida women aged 18–30 years, with gestational ages between 37 and 41 weeks, including both booked and unbooked cases, carrying a singleton fetus in cephalic presentation and in the active phase of labour, were included in the study after

obtaining informed consent. Multigravida women, those with multiple pregnancies, malpresentation, induced labour (postdated prostaglandin use), patients requiring epidural analgesia, those with antepartum haemorrhage, and women with prolonged rupture of membranes (>18 hours) were excluded.

A consecutive convenient non-probability sampling technique was used. The sample size was calculated using OpenEpi based on the mean duration of cervical dilatation in the paracetamol group (4.13 ± 1.63 hours) and the placebo group (5.66 ± 1.85 hours)[13], with a 95% confidence interval and 80% power. The calculated sample size was 21 patients per group (total 42). To compensate for potential dropouts and to ensure adequate statistical power, 200 women were enrolled, with 100 participants allocated to each group.

Participants were randomized into two groups using the lottery method (sealed envelope technique). Group A (control group) comprised 100 women in normal labour who were augmented with oxytocin only at cervical dilatation of 5 cm or more. Group B included 100 women in normal labour in whom labour was augmented with intravenous oxytocin at 5 cm cervical dilatation, along with additional intravenous paracetamol (1000 mg diluted in 100 mL) administered simultaneously.

All participants underwent general, systemic, and obstetric examinations, including vaginal examination. Patients were enrolled into the study protocol upon entering the active phase of the first stage of labour. From this point onward, labour progress was documented using a partogram, and labour was monitored according to standard institutional protocols. All medications were administered following a predefined and accepted drug protocol. Oxytocin augmentation was carried out in all primigravida women using 10 units of oxytocin diluted in 1000 mL of Ringer's lactate, infused intravenously at an initial rate of 10 drops per minute, with increments of 10 drops per minute every 30 minutes as required. Active management of the third stage of labour was practiced in all cases.

Time was recorded in minutes from 5 cm cervical dilatation until delivery of the baby. The partogram was plotted by an obstetrician and served as the baseline reference for monitoring labour progress and evaluating treatment regimens. The attending obstetrician documented all events, including timing and cervical dilatation. Data were entered and analyzed using SPSS software version 21.

Frequencies and percentages were calculated for booking status, while means were calculated for age, gestational age, and duration of cervical dilatation. The two groups were compared using the independent t-test for mean duration of cervical dilatation. Effect modifiers were controlled through stratification, and post-stratification comparisons were made using the independent t-test. A p-value ≤ 0.05 was considered statistically significant.

Results

This study enrolled the 80 women were, with 50 received paracetamol as an intervention to enhance cervical dilatation, improve pain control, and reduce the need for additional analgesics. Overall mean age of the was statistically insignificant across the groups aa mean age was 27.17 ± 3.81 years in group A and 27.95 ± 3.72 years in group B, p = 0.361. Similarly, the mean gestational age was 38.12 ± 1.26 weeks in group A and 37.67 ± 1.09 weeks in Group B p = 0.093. Table I.

Table I: Mean age and mean gestational age comparison in both groups.

Variables	Groups	Mean	SD	p-value
Age	Group A	27.17	3.81	0.361
	Group B	27.95	3.72	
Gestational age	Group A	38.12	1.26	0.093
	Group B	37.67	1.09	

According to BMI, most participants in group A were overweight (45%), followed by normal-weight were 42.5%, obese were 10% and none were underweight, while in Group B, overweight women were also in majority 55%, followed by normal weight were 25%, obese were 17.5%, and only one woman was underweighted 2.5%, as shown in table II.

Table II: BMI comparison in both groups.

	Study groups			p-value
BMI	Group A	Group B	Total	
Normal	17	10	27	0.284
	42.5%	25.0%	33.8%	
Obese	4	7	11	
	10.0%	17.5%	13.8%	
Overweight	18	22	40	
	45.0%	55.0%	50.0%	
Underweight	0	1	1	
	0.0%	2.5%	1.3%	

On the comparison of mean VAS pain scores in Group A patients reported a significantly lower average pain score (4.02 ± 1.16) compared to Group B (5.52 ± 1.64), p = 0.001. The initial dilatation of cervix was similar in both groups (p = 0.400), while after two hours, patients of Group A showed significantly greater cervical dilatation 5.44 ± 1.01 cm compared to Group B 4.95 ± 0.97 cm, p = 0.030. Furthermore, the duration of labor was also noted

significantly shorter in Group A (8.33 ± 1.77 hours) compared to Group B (9.69 ± 2.16 hours), p = 0.003. Table III.

Table III: Mean VAS and cervical dilatation comparison in both groups.

	Group	n	Mean	SD	p-value
Pain score (VAS 0 to10)	Group A	40	5.02	1.16	0.001
	Group B	40	3.52	1.64	
Initial dilatation	Group A	40	3.02	0.61	0.400
	Group B	40	3.88	0.62	
Dilatation after 2 hours	Group A	40	4.95	0.97	0.030
	Group B	40	5.44	1.01	
Duration of labor hours	Group A	40	9.69	2.16	0.003
	Group B	40	8.33	1.77	

Paracetamol group showed superior pain relief compared to control group, as a significantly higher proportion of participants in paracetamol group achieved adequate analgesia (70.0% vs 37.5%**),** while inadequate analgesia was more common in control group **(**62.5% vs 30.0%**)** (p=0.004). Table IV

Table IV: Frequency of adequate analgesia comparison in both groups.

		STUDY GROUPS			p-value
		Group A	Group B	Total	
Adequate analgesia	No	12	25	37	0.004
		30.0%	62.5%	46.3%	
	Yes	28	15	43	
		70.0%	37.5%	53.8%	
Total		40	40	80	
		100.0%	100.0%	100.0%	

Discussion

Labour pain is generally regarded as one of the most intense forms of pain experienced by women. The physiological and psychological responses to this severe pain—along with increased respiratory and cardiovascular activity, neuroendocrine activation, and pain-related behavioural reactions—can adversely affect both maternal and fetal health.[9] Several pain-management modalities are used during labour to reduce discomfort and potentially lower caesarean section rates. Postpartum pain is commonly managed with non-steroidal anti-inflammatory drugs (NSAIDs), while paracetamol is frequently added as an adjunct to opioid analgesics after childbirth. However, the present study specifically evaluated paracetamol versus placebo during labour among primiparous women, focusing on their effects on cervical dilatation and the adequacy of analgesia.

In this study the mean pain score (VAS) in paracetamol administration group found significantly lower 3.02 ± 1.16 compared to the control group 5.52 ± 1.64 (p = 0.001). The findings are consistent with several other recent studies demonstrating greater pain relief with paracetamol administration, like in a placebo-controlled study by El-Maeboud KH et al[8] on analgesia during intrapartum, women underwent IV paracetamol showed significantly lower mean pain scores (VAS) shortly after administration and needed less supplementary medication compared to the controls (14% out of 57 versus 83.1% out of 59) at the various time points (p < 0.001). In aligns to our findings Mushtaq N [11] reported that the paracetamol intervention provided the more effective analgesia, as demonstrated by significantly lower pain scores in contrast to the control group at 1 hour (mean VAS= 4.44 versus 5.55) and at 3 hours (mean VAS= 6.51 versus 6.96), p < 0.001) respectively, indicating the higher pain relief over the observed intervals time. Likewise, Zutshi V et al[14] concluded that the intravenous administration of acetaminophen is effective non-opioid agent for the labor pain management, providing analgesia without significant feto-maternal adverse effects. On the other hand, Marwah M et al[15] also reported that the 1 hour following 1000 mg of intravenous paracetamol administration, showed a significantly less mean VAS score (6.38 ± 0.82) in contrast to Group B (7.34 ± 0.88) p = 0.001. Similarly, at the three hours post-administration, the average pain score continued significantly lower in paracetamol group (7.86 ± 1.20) compared to another group (9.11 ± 0.75), (p = 0.001). Consistently few other studies also reported that the Acetaminophen is an effective non-opioid option for labour analgesia and offers a greater likelihood of providing meaningful intrapartum pain relief, without significant feto-maternal adverse effects.[16-18] Overall, the recent studies align with findings of this study while the degree of advantage fluctuates by study design and comparator drugs status, the reliable trend toward better pain control achievements and favorable labor results supports the role of paracetamol as an reliable,, safe and effective option for intrapartum analgesia.

In this study initial dilatation of cervix was similar in both groups (p = 0.400), while after two hours, patients of paracetamol group showed significantly greater cervical dilatation 5.44 ± 1.01 cm compared to control group 4.95 ± 0.97 cm, (p = 0.030). Additionally, the duration of labor was noted significantly shorter in paracetamol group (8.33 ± 1.77 hours) compared to control group 9.69 ± 2.16 hours), (p = 0.003). Above findings were supported by a randomized trial,[10] were paracetamol group showed significantly shorter 1st and 2nd stages of labor in contrast to controls (p < 0.05), together with lower mean pain scores, indicating not only better analgesia but also potential benefits in the cervical dilatation and overall

progression of the labor.[10] Our findings also corelates with the study by Marwah M et al[15] where intravenous paracetamol reported as effective intrapartum analgesic for both primiparous and multiparous women, and was associated with decreased labour duration, with no evidence of any adverse fetal and maternal outcomes. Consistently few other relevant studies also reported supportive findings.[19,20] Collectively, the studies consistently reported that the administration of paracetamol is linked to the shorter labor durations and enhanced cervical dilatation, supporting its effectiveness as a safe and effective treatment modality for intrapartum pain management and labour progress.

Furthermore, in this study paracetamol group showed superior pain relief compared to control group, as a significantly higher proportion of participants in paracetamol group achieved adequate analgesia compared to control group (70.0% vs 37.5%**),** indicating that the intervention provided more effective in achieving better pain control during labor (p=0.004). Our findings align with other recent studies reporting that intravenous administration of paracetamol significantly decreases the pain score during labor and also decreases the requirement of supplementary analgesia.[21,22] Generally, the available evidence consistently proposes that intravenous administration of paracetamol offers effective labor analgesia, reduction the rescue analgesics requirements, and may positively influence progression of labor. Though, this study has certain limitations, such as relatively limited sample size, single-center study, and without long-term follow-up. However, further large-scale multicenter trials with diverse populations are suggested to further validate the efficacy and safety of in labor, measure ideal dosing procedures, and investigate the impact of it on outcomes of the labour and the maternal satisfaction.

Conclusion

The intravenous administration of paracetamol during active labor among primiparous patients provided the better analgesia significantly in contrast placebo, in terms of evidenced by greater rates of adequate pain relief and lower need for supplementary analgesia. Moreover, the administration of paracetamol was found significantly linked to improved cervical dilatation and shorter duration of the labor, suggestive of a potential positive effect on the progression of labor. Overall findings supported the usage of paracetamol intravenously as an effective, reliable and non-opioid selection for intrapartum management of pain and labor progression. In spite of these encouraging findings, future large-scale, multicenter studies are suggested to authorize these advantages, optimize dosing plans, and estimate the maternal and fetal outcomes more comprehensively.

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