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EFFICACY OF INTRAVENOUS INFUSION OF PARACETAMOL AS INTRAPARTUM LABOUR ANALGESIA

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ABSTRACT

Aim: To evaluate the efficacy of an intravenous infusion of 1000 mg of Paracetamol as intrapartum labour analgesic. **Materials And Methods:** This was a prospective study carried out in Department of Obstetrics and Gynaecology in Rajah Muthiah Medical College and Hospital from 2015-2017 on 60 antenatal mother in active labour, after receiving the ethical clearance and written knowledgeable consent. The first 60 consecutive parturients fulfilling the inclusion standards had been recruited into the study. Women had been then randomised to obtain both intravenous one thousand mg (1000mg) of Paracetamol (Group A, n=30) or intravenous injection of sterile water (Group B, n=30). Both the groups had been observed and compared for time of onset of analgesia, pain intensity was recorded by using Mc Gills scale before ,one and three hours after drug administration, duration of labour, maternal cardio respiratory parameters, mode of delivery, fetal APGAR scores, neonatal outcome and side effects of drugs. **Results:** No difference in pain intensity was visible earlier than drug administration. There was significant pain reduction in paracetamol group after 1 and 3 hour of drug administration ($p<0.001$) when compared to placebo. Total duration of labour from enrolment in study to delivery in the paracetamol group changed was 276 mins (4 hrs36 mins) ± 59.97 minutes and in the placebo group it was 451 minutes (7hrs 31mins) ±82.01 mins suggested that total labour duration was shortened in paracetamol group compared to placebo. Maternal complications like nausea, vomiting was not significant in both groups. APGAR scores in both groups had been satisfactory. **Conclusion**: Intravenous Paracetamol was an efficacious non-opioid drug for relieving labour pain without any significant maternal and foetal adverse effects.

INTRODUCTION

Child birth is allied with very severe pain for most women. Labour pain is among the most intolerable pain experienced by women. Labour pain affects maternal psychology and labour course thus causing apprehension, anxiety, and stress. It includes both sensory component and the vital emotional, motivational and cognitive facets[1]. Pain during the first stage of labour is due to cervical dilatation and uterine muscle wall ischemia resulting in accumulation of lactate. During the late first stage and second stage of labor, the vagina and perineum forms extra sources of pain. Increase in sympathetic activity leads to increased oxygen consumption, minute ventilation during contractions which can cause respiratory alkalosis, and metabolic acidosis and left shift of maternal oxyhemoglobin curve all of which can lead to decreased oxygen transfer to the fetus, prolonged labour and adverse outcome. Thus, pain relief during labour reduces maternal stress and improve maternal and perinatal outcome. Labour pain is a result of many complex interactions, physiological and psychological, excitatory as well as inhibitory. The pain if not adequately controlled may affect respiratory, cardiovascular and gastro intestinal, urinary and neuro endocrine functions due to segmental and suprasegmental reflexes. Pain also reduces uteroplacental blood flow thus leading to altered fetal homeostasis[2].

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The non-pharmacological techniques of analgesia include emotional support,warm water bath, relaxed birth environment, psycho-somatic preparation, yoga, Acupuncture, Transcutaneous electrical nerve stimulation (TENS), Hypnosis, Aromatherapy and Breathing techniques. The commonly used and effective pharmacological techniques include opioids like pethidine, tramadol, morphine, fentanyl, butorphanol, pentazocine, though the regional analgesia is gold standard nowadays and routinely used in modern obstetric anesthesia in developed countries. The newer advances like combined spinal epidurals, low dose epidurals, patient controlled intravenous, inhalational, and epidural analgesia, altered regional analgesia techniques include pudendal block, paracervical block, lumbar sympathetic block, perineal infiltration have revolutionized modern obstetric anesthesia. But most of modern obstetric analgesia practices involve participation of expert anesthesiologist, costly equipment, and continuous monitoring facilities which unfortunately will not 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. However, systemic opioids causes maternal (dysphoria, sedation, respiratory depression, nausea and vomiting and delayed gastric emptying) and fetal adverse effects (fetal distress, early neonatal respiratory depression and behavioural and feeding problems) upto six weeks post-delivery[3]. These concerns led to an exploration of an alternative non-opioid (Paracetamol) for maternal pain relief in labour.

Paracetamol, the mode of analgesic action of which has still not been fully found out is thought to exert its analgesic activity by inhibiting the production of prostaglandins in the Central Nervous System (CNS) (central acting) and peripherally blocking pain impulse[(4,5)]. Also it has serotonergic (5HT) mechanism and cannabinoid agonism mechanism having its impact on analgesic effect, which recently led to the discovery of intravenous preparation[6]. Various studies proved intravenous Paracetamol as effective analgesic agent which is safe, effective, inexpensive, and requires no special monitoring[7].

Paracetamol being cheap and simple to administer could be a boon agent of obstetric analgesia in developing countries like India. Paracetamol is an effective non narcotic analgesic and antipyretic drug with tolerable side effects compared to other opioids and NSAIDs. The use of iv formulations during labour pain relief has an advantage with excellent bioavailability and earlier onset of action with higher mean IV c max (maximum plasma concentration of drug) and an earlier time to maximum concentration (T-max), with less intrasubject variability, compared with other formulations. Studies have documented safety and efficacy of intravenous Paracetamol as a labour analgesic with tolerable adverse effects[(8.9)]. Paracetamol has a favourable safety profile without any risk of congenital anomalies[10]. The widespread use of anti spasmodic helps to ensure progress of labour which reduces the risk of dysfunctional labour enabling early identification of emerging obstetric problem. The requirements of a satisfactory analgesic in labour are safety and effective analgesia throughout the painful periods of labour with no unpleasant maternal side effects and no depressant effect on the baby or on the maternal cardiorespiratory system. The technique used should be cheap, easy to administer, produce good relief of pain but should not impair consciousness and co-operation and should be non toxic to the mother and fetus. The technique must have no tocolytic action and should not delay labour.

So we undertook this study with the aim to study about efficacy and safety of single dose 1000 mg intravenous Paracetamol as labour analgesia during active phase of labour.

MATERIALS AND METHODS

This study was a comparative prospective –randomised study conducted in Department of Obstetrics and Gynaecology in RMMC&H, Chidambaram 2015-2017. A random organization of sixty antenatal women in age group 20 to 35 years with term gestation with cephalic presentation in active phase of labour had been recruited and selected according to inclusion criteria and divided into 2 groups. Antenatal women with previous LSCS, scarred uterus (post myomectomy), multifetal gestation, fetal malpresentation, intrauterine fetal demise, antepartum hemorrhage, clinical diagnosis of CPD were excluded from this study.

Group A-Study Group - 30 women (15 primi+15 multi) in active labour received intravenous infusion containing a thousand mg (1000 mg) of paracetamol single dose over 15 minutes.

Group B-Placebo Group - 30 women (15 primi+15 multi) in active labour received one hundred ml (100 ml) intravenous infusion of normal saline over 15 minutes.

In all women included in this study had undergone detailed history, general, systemic and obstetric examination. Vaginal examination had been done and all the required investigations completed. Labour was monitored using partogram. Pain intensity before administering drug recorded by means of Mc Gills pain intensity scale (table1). Measurement of pain relief was done after 1 and three hour of drug administration. Fetal monitoring performed with the use of a NST. Duration of labour, Mode of delivery, neonatal outcome and drug delivery interval and side effects of drugs in both the groups have been noted.

Table 1 Mc Gills pain intensity scale

Mc Gills scale	Pain intensity
0	No pain
1	Mild pain
2	Discomfort
3	Distressing
4	Horrible
5	Excruciating

Statistical Analysis

Data have been defined as mean ± SD and percent. Metric data had been as compared through student's t test,

whereas non metric information had been compared by means of chi square test and Mann-whitney U check. P<0.05 was taken into consideration as significant p value. Software used was Microsoft excel and statistical package for social sciences for data analysis (SSPS 21).

RESULTS

The mean age group of the women in paracetamol group was 24.86±4.06 years and in the placebo group was 23.47±4.34 years. The difference was not statistically significant among the 2 study groups (p=0.865) (table 2). The mean gestational age in paracetamol group was 39.35±1.73 weeks and in placebo group was 39.73±1.01 weeks. The difference was not statistically significant between the two groups (p=0.995) (table 2).

The mean dilatation and effacement of cervix at enrolment in the paracetamol group had been 4.13±0.34 cms and 61.66±10.85% respectively. In the placebo group, the mean dilatation and effacement of cervix had been 4.22±0.13 cms and 62.01±9.12% respectively without a statistically vast difference (p = 0.226,0.710). (table 2)

Table 2

Parameters	GROUP A	GROUP B	P Value
Maternal Age	24.86±4.06 yrs	23.47±4.34 yrs	0.865(NS) *
Gestational Age	39.35±1.73 Weeks	39.73±1.01 weeks	0.995(NS) *
Cervical Effacement	61.66 ±10.85 %	62.01±9.12%	0.710(NS) *
Cervical Dilatation	4.13 ±0.34 cms	4.22 ± 0.13 cms	0.226(NS) *

*Non significant

Pain intensity before drug administration: Using Mc Gills pain scale, 9 women (30%) in the paracetamol groups had horrible pain, 18 women (60%) had distressing pain, and 3 women (10%) had discomfort at the point of entry into study. In the placebo group, 7 women (23.33%) had horrible pain, 19 women (63.33%) had distressing pain, and 4 women (13.33%) had discomfort. The pain intensity was measured using McGills scale among the two groups before drug administration had been statistically insignificant (p = 0.781) (Table 3).

Table 3 Pain Intensity Measurement

Time	Pain intensity	Intravenous paracetamol group		Placebo group		*p* value
		N	%	N	%	
Before drug administration	Mild	0	0.0	0	0.00	0.781 (NS)*
	Discomfort	3	10.0	4	13.33	
	Distressing	18	60.0	19	63.33	
	Horrible	9	30.0	7	23.33	
After 1 h of drug administration	Mild	3	10.0	0	0.00	<0.001 (Sig) †
	Discomfort	22	73.4	1	3.33	
	Distressing	4	13.3	17	56.67	
	Horrible	1	3.3	12	40.00	
After 3 h of drug administration	Mild	9	30.0	2	6.67	<0.001 (Sig) †
	Discomfort	17	56.7	1	3.33	
	Distressing	4	13.3	11	36.67	
	Horrible	0	0.0	16	53.33	

† Significant
* Non - significant

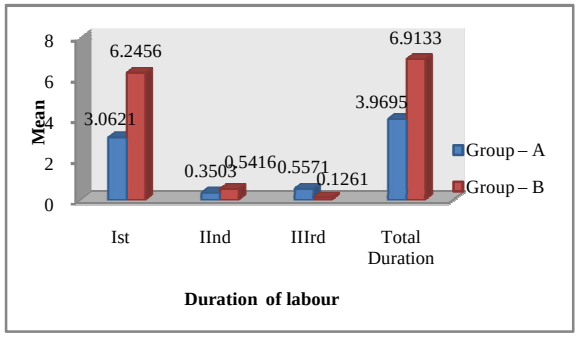
After 1 h of intravenous paracetamol administration, 1 women (3.3%) had horrible pain, 4 women (13.3%) had distressing pain, 22 women (73.4%) had discomfort, and 3 women (10%) had mild pain. In the placebo group, 12 women (%) had horrible pain, 17 women (56.67%) had distressing pain, 1 women (3.33%) had discomforting pain, and no women had mild pain after 1 h of drug administration. The difference between the two groups had been statistically significant. (p<0.001) (Table 3). After 3 h of paracetamol administration, 4 women (13.3 %) had distressing pain, 17 women (56.7 %) had discomforting pain, and 9 women (30%) had mild pain. In the placebo group, 16 women (53.33%) had horrible pain, 11 women (36.67%) had distressing pain, 1 women (3.33%) had discomfort and 2 women (6.67%) had mild pain measured using Mc Gills pain intensity scale. The difference among the two groups had been statistically significant (p<0.001) (Table 3).

Women who had lower segment caesarean section (LSCS) were excluded from study about efficacy of pain and duration of labour. The mean duration of active phase of first stage of labour in the paracetamol group was 196mins (3hrs 16mins) ±56 minutes and in the placebo group turned into 264 mins (6hrs 24mins) ±86 mins. The difference in mean duration of the active phase of first stage of labour was statistically significant (p<0.001). (Table 4/Graph 1) The mean duration of the second stage of labour within the paracetamol group became 35.03±7.5 minutes and in the placebo group it was 54.16 ±40 minutes .The mean duration of second stage of labour became statistically significant (p<0.001) between 2 groups. (Table 4/Graph 1). The mean duration of 3rd stage of labour in the paracetamol group was 5. 57±0.95 mins and within the placebo group it was 12.34±1.26 mins. The difference in the mean duration of third stage of labour was statistically significant between the two groups (p<0.001) (Table 4/Graph 1). Total duration of labour from enrolment in the paracetamol group was 276 mins (4hrs 36mins) ±59.97mins and in the placebo group, it was 451 mins (7hrs 31mins) ± 82.01 mins. The distinction was statistically significant among the two groups (p<0.001). (Table 4/Graph 1)

Table 4 Duration of Labour

Duration of labour	Group – A (IV Paracetamol - 1000mg)		Group – B (Placebo group)		t-test value	P value
	Mean	Std. Deviation	Mean	Std. Deviation		
Ist	3.0621	0.56254	6.2456	0.8651	16.543	<0.001(S) †
IInd	0.3503	0.7510	0.5416	0.4097	6.548	<0.001(S) †
IIIrd	0.5571	0.0959	0.1261	0.2672	22.456	<0.001(S) †
Total Duration	3.9695	0.59978	6.9133	0.82011	18.356	<0.001(S) †

†Significant



Graph 1 Duration of Labour

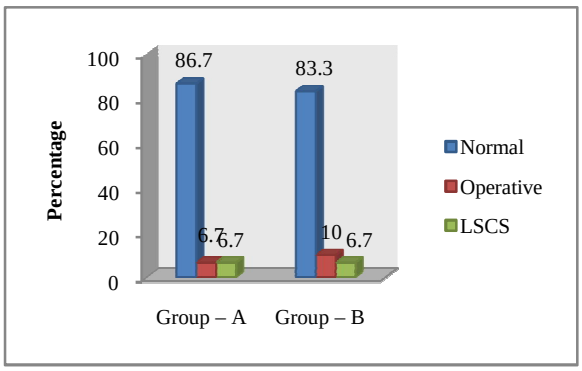
Drug delivery interval in the paracetamol group was 233 mins (3hrs 53mins) ±44.13 minutes and within the placebo group was 422 mins (7hrs 2mins) ± 53.21mins. The difference was statistically significant between the groups (p<0.001).(table 5)

Table 5 Drug Delivery Interval

Group	N	Mean	Std. Deviation	t-test value	P value
Group – A (IV Paracetamol - 1000 mg)	30	3.5353	0.44131	17.654	<0.001(S) †
Group – B Placebo group	30	6.6283	0.53211		

†Significant

26 (86.7 %) women within the paracetamol group and 25(83.3%) in the placebo group had spontaneous vaginal delivery. 2 (6.7%) women in paracetamol and 2 (6.7%) women in placebo group had to undergo LSCS. There had been 2(6.7%) instrumental deliveries in paracetamol group and 2(6.7%) instrumental deliveries in placebo group. No statistically significant difference in the mode of delivery had been determined between the two groups (p=0.684) (Graph 2).



Graph 2 Mode of Delivery

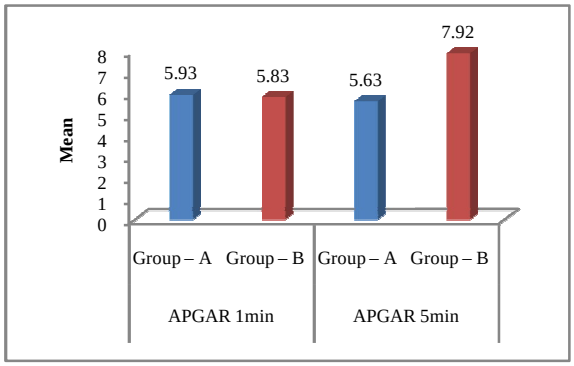
In the paracetamol group, nausea was observed in 6.67% followed by vomiting (3.33%). Nausea was commonest adverse effect within the placebo group (10.0%) followed by vomiting (3.33%). No women in the paracetamol and placebo group had PPH, and fetal tachycardia/ bradycardia, respiratory depression. The variation in the nausea and vomiting were statistically insignificant among the 2 groups (p = 0.645) (Table 6).

Table 6 Maternal Complications

Maternal Complication	Group- A (IV Paracetamol – 1000 mg)		Group - B (Placebo group)	
	N	%	N	%
None	27	90.00	26	86.67
Nausea	2	6.67	3	10.00
Vomiting	1	3.33	1	3.33
PPH	0	0.00	0	0.00
Total	30	100.0	30	100.00

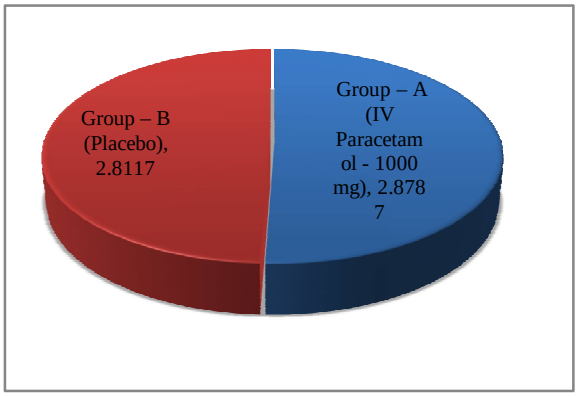
P value 0.645(Non significant)

The mean APGAR scoring of neonates in the paracetamol group at 1 min was 5.93 ± 1.17 and at 5 min was 7.83 ± 0.86. The mean APGAR score of the neonates in the placebo group at 1 min was 5.63 ± 0.81 and at 5 min was 7.92 ± 0.77. The difference had been statistically insignificant (p-0.714, 0.0621)(Graph 3).



Graph 3 Apgar Scores

The mean birth weight was 2.87 ± 0.43 kg within the paracetamol group and 2. 89 ± 0.20 kg in the placebo group. The distinction were statistically insignificant among the 2 groups (p =0.499)(Graph 4).



Graph 4 Birth Weight Mean

DISCUSSION

Paracetamol also called as acetaminophen or APAP (N-acetyl-para-aminophenol). Molecular system is $C_8H_9NO_2$. The probable mode of analgesic action of intravenous paracetamol was peripheral and central inhibition of COX and or interaction with serotonergic system. 1 gram of intravenous paracetamol have to receive only if body weight is more than 33 kg and hepatic issues ruled out. The dose needed should no longer be repeated within four hours and ought to no longer exceed 4gms in 24 hours.

The findings of present study suggest that paracetamol group had a significant decrease in pain intensity 1 and 3 hour after drug administration as compared to normal saline. About 75% women in paracetamol group has substantial relief of pain which lasted for atleast 3 hours**.** Meenakshi Lallar *et al* (2015)[11], Hema Mohan *et al* (2015)[12], Bishnu Prasad *et al*(2013)[13] also found to have pain relief after 1 and 3 hour of drug administration.This might be explained by the fact that peak analgesic effect of Paracetamol is seen at 1 hour where its effect lasting for 4 to 6 hours.

There was a statistically significant reduction in duration of first, second and third stages of labour after administration of intravenous Paracetamol. Jeetinder Kaur Makkar *et al* (2014)[14] found significant decrease in duration of first stage of labour. A good analgesic will

reduce the duration of labour and prevent dysfunctional labour.

In study conducted by Vijay Zutshi *et al*,[15] (2016) evaluated the efficacy of an intravenous infusion of 1000 mg of Paracetamol as an intrapartum analgesic. There was pain reduction at 1 and 2 hours in both groups ($p<0.001$). However, it was more significant in the Paracetamol group, especially at 1 hour. Duration of labour was shortened, without any maternal and foetal adverse effects. In their study, it was demonstrated that Intravenous Paracetamol was an efficacious nonopioid drug for relieving labour pain without any significant maternal and foetal adverse effects.

In a study by Elbohoty *et al*. in 2012[(8)], intravenous Paracetamol infusion was compared with intravenous Pethidine for labour analgesia. It was concluded that effectiveness of intravenous Paracetamol and duration of action were comparable in both drugs, but Paracetamol was associated with a fewer maternal side effects and also shortened labour.

In another study by Abdollahi *et al*. in 2014[(7)], comparing intravenous paracetamol with intramuscular pethidine, it was concluded that intravenous paracetamol was more effective. But no shortening of labour was observed with intravenous paracetamol and no difference in maternal and neonatal outcome.

In study by Karim *et al*[16], (2015) evaluated the efficacy and adverse effects of an i.v. infusion of paracetamol during the active phase of labor as compared with sterile water (placebo) as a method for intrapartum analgesia. They found that Paracetamol appears to be a safe and effective medicine that can be used during the intrapartum period.

These studies gives us an interpretation that intravenous Paracetamol might be a better analgesic than other systemic opioids.

Jeetinder Kaur Makkar (2014) *et al* [(13)], in their study noted foetal bradycardia in 5 patients in tramadol group (17.2%) as compared to 2 in paracetamol group (6.6%). No maternal adverse effects were noted with paracetamol, confirming its favourable safety profile.

Neonatal outcome was more favourable with paracetamol. The mean Apgar scores at 1 and 5minutes were favourable, indicating absence of any neonatal adverse effects with the use of Paracetamol.

In our study, Neonatal outcome was beneficial with paracetamol, however no other principal complications occured with paracetamol. Thus it was proved that intravenous paracetamol was most efficacious and has safety profile in labouring women.

CONCLUSION

Obstetric analgesia helps in making childbirth a favourable and painless event. Findings from the present study demonstrated that intravenous paracetamol is an effective non opioid drug for relieving labour pain. Paracetamol also helps in shortening the length of labour and has fewer maternal adverse effects; however neonatal outcome of Paracetamol was excellent. So from our study we can conclude that intravenous Paracetamol is simple, cost effective, feasible option as labour analgesics. In developing countries like India, where health care resource settings were poor, intravenous Paracetamol can be used as a labour analgesic due to its good analgesic action, shortening of labour, and fewer maternal side effects. This was in accordance with the study of Malaise O shows that IV Paracetamol has good efficacy and safety in labour analgesia. Also, the effect of Paracetamol in reducing duration of labor necessitates future research, with potential benefits being,

1. lowering the incidence of complications due to lengthened labour (neonatal sepsis or maternal infection such as chorioamnionitis or puerperal sepsis)
2. Advantageous in decreased foeto-placental reserve, reducing the occurrence of abdominal delivery;
3. Reducing the time of labour would be welcomed by women and health authorities with limited medical resources especially in developing countries.

Though it was said that memories of pain fade consistently, this does not make it any more tolerable at times. It is therefore only humane to attempt to relieve it and make labour more memorable and favourable event for the women.

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