# Efficacy of intravenous infusion of paracetamol as an intrapartum labour analgesia

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**Manuscript submitted – 19th September 2021**
**Peer review completed – 28th January 2022**
**Accepted for Epub – 6th February 2022**



**Abstract:**

**Aim:** To evaluate the efficacy of an intravenous infusion of 1000 mg of paracetamol as intrapartum labour analgesic. **Methodology:** This was a prospective study carried out in department of Obstetrics and Gynaecology in SMGS Hospital, Government Medical College, Jammu for a period of one year during 2019-2020 on 200 antenatal mother in active labour, after receiving the ethical clearance and written consent. The first 100 patients 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=100) or intravenous injection of sterile water (Group B, n=100). 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 cardiorespiratory 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 259.97 (4 hrs18 mins) ± 14.47 minutes and in the placebo group it was 461 minutes (7 hrs 68 mins) ± 66.01 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.

**Keywords:** Labour, intravenous paracetamol, intrapartum analgesia.

Labor pain is a result of many complex interactions, physiological and psychological, excitatory as well as inhibitory [1]. The pain if not adequately controlled may affect respiratory, cardiovascular, gastrointestinal, urinary and neuro-endocrine functions due to segmental and supra segmental reflexes. Pain also reduces uteroplacental blood flow leading to altered fetal homeostasis [2]. Adequate analgesia during labour has a positive influence on the course of labour [3].

Labour pain is among the most excruciating pain experienced by women. Pain during the first stage of labor is caused by stretching of the lower uterine segment (LUS) and cervix, which stimulates the mechanoreceptors. During the late first stage and second stage of labor, the vagina and perineum form additional sources of pain. The

Majotra N, Parehar P, Jaggi R. Efficacy of intravenous infusion of paracetamol as an intrapartum labour analgesia. The New Indian Journal of OBGYN. 9th August 2022. Epub Ahead of Print.

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.

The ideal labour analgesia technique should dramatically reduce the pain of labour, while allowing the parturient to actively participate in the birthing experience [4]. In addition, it should have minimal effect on the fetus or the progress of labour. Non pharmacological methods of pain relief during labour include:

- Psychoprophylaxsis - hypnosis, breathing exercises
- Environmental modifications-presence of relatives, music etc.
- Physical modalities- massaging, heating pads, warm bath
- Acupuncture
- Transcutaneous electrical nerve stimulation (TENS)

The newer advances like combined spinal epidurals, low dose epidurals, patient-controlled intravenous, inhalational and epidural analgesia have revolutionized obstetric anaesthesia [5]. But most of modern obstetric analgesia practices involve participation of expert anaesthesiologist, 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.

The probable mode of analgesic action of intravenous paracetamol is peripheral and central inhibition of COX or interaction with serotonergic system. 1 gram of intravenous paracetamol have to be given only, if body weight is more than 33 kg and hepatic issues ruled out. The peak analgesic effect of paracetamol is seen at 1hr and effect lasts for 4 to 6h while for intramuscular tramadol, onset is within 10min and action lasts for 2-3 hours [6].

Various studies have proved intravenous paracetamol as effective analgesic agent which is safe, effective, inexpensive, and requires no special monitoring. [7-10] However, there are no significant trials regarding paracetamol analgesic effect 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 agent of obstetric analgesia in developing countries. Only a few studies have documented safety and efficacy of intravenous paracetamol as a labor analgesic. So, undertook the study to evaluate effect of paractamol in labour analgesia.

**Materials and methods**

The study was conducted in the postgraduate department of Obstetrics and Gynaecology, SMGS Hospital, Government Medical College, Jammu for a period of one year during 2018-2019. Two hundred (200) primigravidae women in age group 20-35 yrs were selected from those who were admitted in obstetrics emergency ward of SMGS Hospital. The particulars of the patients were noted according to prescribed proforma.

Inclusion criteria -
Primigravida.
Single live intrauterine foetus.
Spontaneous onset of labor.
Cephalic presentation.
37 completed weeks of gestation.

Active phase of labor (Active phase of labour is described as cervical dilatation more than or equal to 3cm, cervical effacement more than or equal to 60% and uterine contractions.)

Exclusion criteria -
Gestational age <37 completed weeks.
Multigravidas.
Women in latent phase of labor.
With medical disorders and obstetric complications.
Scarred uterus.

Clinical evidence of cephalopelvic disproportion.
History of allergy to any opioid or hypersensitivity to the drugs.

Group A (Study group) - 100 women, in active labour received intravenous infusion containing 1000 mg of paracetamol single dose over 15 minutes.

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

Pain intensity before administering drug was recorded by Mc Gills pain intensity scale. Women included in study, were evaluated with detailed history, general physical examination and obstetric examination, including vaginal examination were done and all the required investigations were carried out. Labour was monitored using partograph (paperless). Measurement of pain relief was done with measurement of pain relief was done with Mc Gills pain intensity scale after 1 and 3 h of drug administration. Foetal monitoring was done using a non-stress test. Mode of delivery, neonatal outcome, duration of labour, drug delivery interval and side effects of drugs in both the groups were noted. At the end of study, data was compiled and analysed using t-test and chi-square statistical test. The pain scale used in the study was **"**Mc Gills pain intensity scale" (table 1).

**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.

**Results**

The mean age group of the women in paracetamol group was 25.71±3.32 years and in the placebo group was 26.21±3.07 years. The difference was not statistically significant among the 2 study groups (p=0.27). The mean gestational age in paracetamol group was 38.76±1.05 weeks and in placebo group was 38.50±1.52 weeks. The difference was not statistically significant between the two groups (p=0.16) (table 2).

**Table 2: Maternal age and gestational age**

| **Categories** | **Maternal age** | | | **Gestational age** | | |
|---|---|---|---|---|---|---|
| | **Mean** | **Standard Deviation (SD)** | **p-value** | **Mean** | **Standard Deviation (SD)** | **p-value** |
| Paracetmol group | 25.71 | 3.32 | 0.27 | 38.76 | 1.05 | 0.16 |
| Placebo group | 26.21 | 3.07 | (N.S) | 38.50 | 1.52 | (N.S) |

The mean dilatation and effacement of cervix at enrolment in the paracetamol group had been 3.55±0.62 cms and 68.10 ±8.25 % respectively. In the placebo group, the mean dilatation and effacement of cervix had been 3.59 ±0.64 cms and 67.9±7.56 % respectively without a statistically vast difference (p = 0.65,0.858**)** (table 3).

**Table 3: Mean dilatation and effacement**

| **Parameters** | **Paracetamol group** | **Placebo group** | **p-value** |
|---|---|---|---|
| Dilatation | 3.55 ± 0.62 | 3.59 ± 0.64 | 0.65 ( N.S) |
| Effacement | 67.9 ± 7.56 % | 68.1 ± 8.25 % | 0.858 (N.S) |

| **Table 4: Pain intensity before, after and 3 hour drug administration** | | | | | | |
|---|---|---|---|---|---|---|
| **Time** | **Pain intensity** | **Paracetamol group** | | **Placebo group** | | **p-value** |
| | | **N** | **%** | **N** | **%** | |
| Before drug administration | Mild | 0 | 0% | 0 | 0% | 0.15 (N.S) |
| | Discomfort | 10 | 10% | 4 | 4% | |
| | Distressing | 66 | 66% | 64 | 64% | |
| | Horrible | 24 | 24% | 32 | 32% | |
| After 1 hour of drug administration | Mild | 5 | 5% | 0 | 0% | 0.001 (S*) |
| | Discomfort | 45 | 45% | 15 | 15% | |
| | Distressing | 45 | 45% | 66 | 66% | |
| | Horrible | 5 | 5% | 19 | 19% | |
| After 3 hour of drug administration | Mild | 31 | 31% | 3 | 3% | 0.001 (S*) |
| | Discomfort | 50 | 50% | 19 | 19% | |
| | Distressing | 18 | 18% | 57 | 57% | |
| | Horrible | 1 | 1% | 21 | 21% | |

Using Mc Gills pain scale, 24 women in the paracetamol groups had horrible pain, 66 women had distressing pain, and 10 women had discomfort at the point of entry into study. In the placebo group, 32 women had horrible pain, 64 women had distressing pain, and 4 women had discomfort (table 4). The pain intensity was measured using Mc Gills scale among the two groups before drug administration had been statistically insignificant (p = 0.781).

After 1 h of intravenous paracetamol administration, 5 women had horrible pain, 45 women had distressing pain, 45 women had discomfort, and 5 women had mild pain. In the placebo group, 19 women had horrible pain, 66 women had distressing pain, 15 women 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 4)**.**

After 3 h of paracetamol administration, 1 women had horrible pain, 18 women had distressing pain, 50 women had discomforting pain, and 31women had mild pain. In the placebo group, 21 women had horrible pain, 57 women had distressing pain, 19 women had discomfort and 3 women had mild pain measured using Mc Gills pain intensity scale. The difference among the two groups had been statistically significant (p<0.001) (table 4)**.**

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 219.35 (3hrs 65mins) ±15.27 minutes and in the placebo group turned into 322.52 (5 hrs 38mins) ± 20.96 mins. The difference in mean duration of the active phase of first stage of labour was statistically significant (p<0.001) (table 5).

| **Table 5: Duration of labour** | | | | | | |
|---|---|---|---|---|---|---|
| **Duration of labour** | **Paracetamol group** | | **Placebo group** | | **t - test** | **p - value** |
| | **Mean** | **S.D** | **Mean** | **S.D** | | |
| 1st Stage | 219.35 | 15.27 | 322.52 | 20.96 | 39.78 | 0.0001 (S*) |
| 2nd Stage | 35.26 | 5.13 | 42.77 | 2.09 | 13.55 | 0.01 (S*) |
| 3rd Stage | 6.23 | 1.34 | 7.198 | 1.55 | 4.72 | 0.0001 (S*) |
| Total | 259.97 | 14.47 | 371.34 | 19.50 | 45.86 | 0.0001 (S*) |

The mean duration of the second stage of labour within the paracetamol group became 35.26±5.13 minutes and in the placebo group it was 42.77 ± 2.09 minutes. The mean duration of second stage of labour became statistically significant (p<0.001) between 2 groups (table 5).

The mean duration of third Stage of labour in the paracetamol group was 6.23±1.34 mins and within the placebo group it was 7.198 ±1.55 mins. The difference in the mean duration of third stage of labour was statistically significant between the two groups (p<0.001) (table 5).

Total duration of labour from enrolment in the paracetamol group was 259.97(4 hrs 33 mins) ±14.47 mins and in the placebo group, it was 371.34 mins (6 hrs19 mins) ±19.50 mins. The distinction was statistically significant among the two groups (p<0.001) (table 5).

Drug delivery interval in the paracetamol group was 2hrs 92min ± 0.32 minutes and within the placebo group was 3 hrs 27 mins ± 0.60 mins.The difference was statistically significant between the groups (p<0.001) **(**table 6**).**

| **Table 6: Drug delivery interval** | | | | | |
|---|---|---|---|---|---|
| **Group** | **N** | **Mean** | **SD** | **t-test** | **p-value** |
| Paracetamol group | 100 | 2.92 | 0.32 | 5.14 | 0.0001 (S*) |
| Placebo group | 100 | 3.27 | 0.60 | | |

The mean Apgar scoring of neonates in the paracetamol group at 1 min was 8.39 ± 1.02 and at 5 min was 9.88±0.36. The mean Apgar score of the neonates in the placebo group at 1 min was 8.39±1.02 and at 5 min was 9.91±0.35. The difference had been statistically insignificant (table 7).

| **Table 7: Mean Apgar score at 1 min and 5 min** | | | | |
|---|---|---|---|---|
| **Group** | **Apgar 1 min** | | **Apgar 5 min** | |
| | **Mean** | **SD** | **Mean** | **SD** |
| Placebo group | 8.47 | 1.10 | 9.88 | 0.36 |
| Paracetamol group | 8.39 | 1.02 | 9.91 | 0.35 |
| t-value | 1.022 | | 0.5975 | |
| p-value | 0.594 (N.S) | | 0.55 (N.S) | |

The mean birth weight was 2.54 ± 0.25 kg within the paracetamol group and 2.62 ± 0.32 kg in the placebo group. The distinction was statistically insignificant among the 2 groups (p 0.0502) (table 8).

| **Table 8: Mean birth weight in both groups** | | | |
|---|---|---|---|
| **Groups** | **Birth weight** | | **p - value** |
| | **Mean** | **SD** | |
| Paracetamol group | 2.54 | 0.25 | 0.0502 |
| Placebo group | 2.62 | 0.32 | (NS) |

In the Paracetamol group, nausea was seen in 3% followed by vomiting in 3%. No women in the paracetamol had respiratory depression, foetal tachycardia. However, foetal bradycardia was seen in 2% of women in paracetamol group. Out of 100, 92 women (92%) in the paracetamol group and 91 in the placebo (91%) had spontaneous vaginal delivery. 7 (7%) women in the paracetamol group had LSCS and 8(8%) women in the placebo group had to undergo LSCS. One woman in the paracetamol group, had ventouse assisted vaginal delivery. Mode of delivery in both groups was primarily vaginal delivery. No statistically significant difference in the mode of delivery had been determined between the two groups (p=0.684) (figure 1).

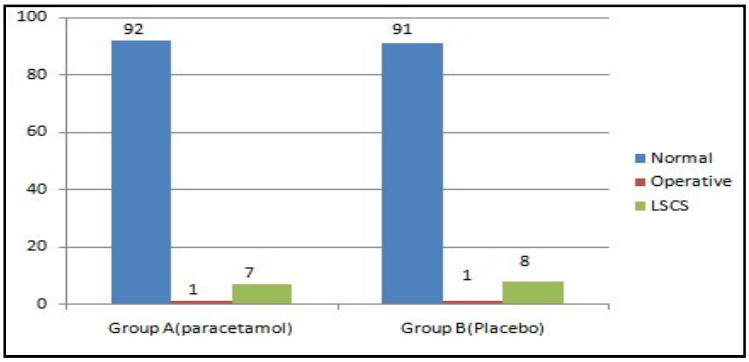


**Figure 1: Mode of delivery in both groups**

**Discussion**

The findings of the present study suggest that paracetamol group had a significant decrease in pain intensity 1 and 3 hrs after intravenous paracetamol administration as compared to intramuscular tramadol group.

About 75 % women in the paracetamol group had substantial relief of pain which lasted for 3 hrs. This might be explained by the fact that peak analgesic effect of paracetamol is seen at 1 hrs and effect lasts for 4 to 6 hrs. There was a statistically significant reduction in the duration of first, second, and third stages of labor after administration of intravenous paracetamol. Hence total duration of labor was reduced in patients who received paracetamol. Drug to delivery interval as stated earlier was 2hrs 92min ± 0.32 minutes in paracetamol group. More studies are required to elucidate the effect of intravenous paracetamol on labor duration, because a decrease in labor duration has multiple potential benefits and better maternal and perinatal outcome. Neonatal outcome was favourable with paracetamol. However, side effects like nausea and vomiting were observed in paracetamol group, but no other major complications occurred with it.

Our results were quite similar to studies conducted by Meenakshi Lallar et al [11] and Hema Mohan et al[10] who found that paracetamol group had a significant decrease in pain intensity at 1 and 3hours after intravenous paracetamol administration.

Elbohoty et al [12] in his study using paracetamol as an intrapartum analgesic randomized primiparous women to receive pethidine or paracetamol. They observed analgesic effect of paracetamol lasted for at least 2 hours and was better than pethidine. Also in the study conducted by Jeetinder Kaur Makkar et al [13] there was significant decrease in duration of first stage of labour in the paracetamol group as compared to the tramadol group.

In another study by Abdollahi et al [14] in 2014, comparing intravenous paracetamol with intramuscular pethidine, it was concluded that intravenous paracetamol was more effective. But no shortening of labor was observed with intravenous paracetamol and no difference in maternal and neonatal outcome.

Abinaya A et al [3] (2017) conducted the study to evaluate the efficacy of an intravenous infusion of 1000 mg of paracetamol as intrapartum labour analgesic and conclude that intravenous paracetamol is simple, cost effective, feasible option as labour analgesics.

These studies gives us an interpretation that intravenous paracetamol might be a better analgesic than other systemic opioids. However, there are limited studies available comparing intravenous paracetamol with intramuscular tramadol for labor analgesia in our knowledge, but it has already been seen in many studies that tramadol is a weaker labor analgesic than pethidine but has a better safety profile [15-17]. More studies are required to elucidate the analgesic profile of intravenous paracetamol in labor as on initial studies it appears to be quite promising.

**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. Larger studies in this regard could further help establish the efficacy and safety of these drugs.

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**Conflict of interest:** None. **Disclaimer:** Nil.