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Comparative Study between Intravenous Paracetamol and Intramuscular Tramadol as Labour Analgesic

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Abstract: ***Purpose: This study was done to compare the efficacy of intravenous paracetamol and intramuscular tramadol injection as labour analgesic. Method: This prospective-randomized study was conducted in 200 primigravidae at term pregnancy in active labour, distributed into two groups of 100 women each receiving single dose of intravenous 1000mg Paracetamol and other 100mg intramuscular tramadol. Pain intensity was recorded by Visual Analogue Scale before, one and three hours after drug administration. Labour events were recorded in partograph. Perinatal outcome and maternal complications were observed. Results: VAS score was divided into four parts: no pain (VAS score 0cm), mild pain (VAS score 0.1-3.9cm), moderate pain (VAS score 4-6.9cm) and severe pain (VAS score 7-10cm). Difference in pain intensity was absent before drug administration. After 1 hour of drug administration, in paracetamol group, severe pain 32.7%, moderate pain 57.1% and mild pain 10.2%. In tramadol group, severe pain 52%, moderate pain 44.9% and mild pain 3.1%. After 3 hours of drug administration, in paracetamol group, severe pain 37.8%, moderate pain 46.9% and mild pain 15.3%. In tramadol group, severe pain 58.2%, moderate pain 39.8% and mild pain 2.04%. Differences in the VAS score between the groups were statistically significant. Mean labour duration in paracetamol and tramadol group – 4hrs38min±51.25mins and 5hrs42mins±58.16mins respectively. Complications – in paracetamol group, 5% nausea, 2% vomiting and 5% PPH (mainly traumatic) while in Tramadol group, 9% nausea, 5% vomiting and 3% PPH and 1 NICU admission in tramadol group. Conclusion: Intravenous paracetamol is a more effective labour analgesic. It shortens labour with fewer maternal and foetal adverse effects as compared to intramuscular tramadol.***

Keywords: Intravenous paracetamol, Intramuscular tramadol, Labour analgesic

1. Introduction

"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" – Moir

Labour signifies one of the most happy as well as one of the most painful moments in a woman's life, labour pain being the most excruciating pain ever experienced by any woman. Thus if not dealt properly, labour can lead to unpleasant experiences, mental agony and stress. Every parturient should be educated prenatally about labour and various modalities available for helping her. Advances in the field of labour analgesia have tread a long journey from the days of ether and chloroform to the present day practice of comprehensive program of labour pain management using evidence based medicine with regional analgesia being gold standard nowadays and routinely used in developed countries (1). But most modern obstetric analgesic practices require the participation of expert anaesthesiologist, costly equipment and continuous monitoring facilities which unfortunately cannot be availed in routine obstetric practice in the developing countries like India, where a majority of obstetric services are in the hands of trained nurses and non specialist doctors. Here comes into picture, the drugs like paracetamol and opiods like tramadol hydrochloride in the field of labour analgesia, especially in the developing countries like ours.

Tramadol hydrochloride, a centrally acting analgesic opioid, is commonly used in labour analgesia in developing countries as it is inexpensive, no special monitoring is required and has been widely studied and proved for its safety and efficacy in labour analgesia as compared to other opiods (2) (3) (4). However there are still controversies regarding its high placental permeability and maternal and neonatal side effects, among many authors. These side effects make some of the healthcare providers reluctant to administer tramadol to women in labour, and so women often labour without any form of analgesia with its attendant risks. In such situations it would be better to use an equally or more effective but a much safer analgesic for pain relief in labour.

Paracetamol, the mode of analgesic action of which has still not been fully elucidated but probably is a centrally acting drug, mainly inhibits prostaglandin synthesis and/or interaction with the serotonergic system. Various studies have proved intravenous paracetamol as an effective analgesic agent which is safe, inexpensive and requires no special monitoring (5) (6) (7). But there are very few trials regarding paracetamol analgesic effect on labour pain in women (8) (9) (10) (11).

We undertook this hospital based prospective randomised study with the aim to compare efficacy and safety of single dose 1000mg intravenous paracetamol with 100mg

intramuscular tramadol hydrochloride as labour analgesic in primigravidae women during active phase of labour.

2. Materials and Methods

The present study was a single-blinded prospective-randomized study conducted in 200 primigravidae women in Gauhati Medical College and Hospital, Guwahati, during the year 2015-2016. Inclusion criteria were primigravidae with full-term pregnancy with spontaneous onset of labour with single foetus in vertex presentation in active phase of labour and those willing to participate after counselling and obtaining written and informed consent. Women with clinical evidence of cephalo–pelvic disproportion, malpresentation, multiple pregnancies, previously scared uterus (post myomectomy), preterm labour, induced labour, antepartum haemorrhage, pregnancy induced hypertension, history of drug allergy, medical disorders, foetal distress and intrauterine foetal death were excluded from the study. After taking informed consent, proper history and examination, the women were randomly distributed in two groups, Group A (Paracetamol)—100 women and Group B (Tramadol)—100 women. All the women in paracetamol group received a 100ml intravenous infusion containing 1000 mg of paracetamol single dose over 15min, and all the women in the tramadol group were given tramadol hydrochloride 100mg intramuscular single dose in upper and outer quadrant of gluteal region with a 2ml syringe. Pain intensity before administering drug was recorded Visual Analogue scale. The VAS score was further divided as: 0cm: no pain, 0.1-3.9cm: mild pain, 4-6.9cm: moderate pain and 7-10cm: severe pain. Labour was monitored using a WHO modified partogram. Measurement of pain relief was done by VAS score after 1 and 3h of drug administration. Mode of delivery, neonatal outcome, duration of labour, drug delivery interval, and side effects of drugs in both the groups were noted. Data were described as mean ±SD and percentage. Metric data were compared by Student's t test, whereas Non-metric data were compared by Chi square test. P<0.05 was considered as significant p value. Software used was Microsoft Office and Excel 2007 and GraphPad Prism version 6.01 for data analysis.

3. Results

The age group in the study, ranged from 18 to 35 years in both groups with mean and SD being 21.72±2.92yrs and 22.36±3.56yrs in paracetamol and tramadol groups respectively. The difference was not statistically significant (p=0.166). The mean gestational age in paracetamol group was 38.44±1weeks and in tramadol group was 38.41±1.03weeks. The difference was statistically insignificant between the two groups (p=0.8347). (Table 1)
The mean dilatation and effacement of cervix at enrolment in the paracetamol group were 4.52±0.85cms and 80.8±16.31% respectively. In the tramadol group, the mean dilatation and effacement of cervix were 4.53±0.89cm and 79.7±15.66%, respectively with no statistically significant difference (p =0.9353, 0.6272). (Table 1)

Table 1: Showing mean dilatation and effacement of cervix

	Group A(Paracetamol)		Group B(Tramadol)		P value
	Mean	SD	Mean	SD	
Age in years	21.72	± 2.92	22.36	±3.56	0.166
Gestational age in weeks	38.44	±1	38.41	±1.03	0.8347
Dilatation of cervix in cm	4.52	±0.85	4.53	±0.89	0.9353
Effacement of cervix in %	80.8	±16.31	79.7	±15.66	0.6272
Birth weight in kg	2.73	±0.31	2.72	± 0.33	0.8254

The mean VAS score decreased significantly from 8.2 (before drug administration) to 6.0 (after 1 hour of drug administration) and 5.6 (after 3 hours) in paracetamol group. Whereas, in tramadol group, VAS score decreased from 8.3 (before drug administration) to 6.8 (after 1 hour of drug administration) and continued to be 6.6 even after 3 hours of tramadol administration. The difference was statistically significant. (Table 2)

Table 2: Showing mean VAS score at different intervals

Mean VAS in cm	Group A		Group B		P value
	mean	SD	mean	SD	
Before drug administration	8.2	±1.06	8.3	±1.05	0.5078
After 1hour of drug administration	6.0	±1.43	6.8	±1.14	<0.0001
After 3hours of drug administration	5.6	±1.43	6.6	±1.54	<0.0001

In paracetamol group, before drug administration, 75.5% of women had severe pain, 24.5% had moderate pain and none had mild or no pain. In tramadol group, 79.6% of women had severe pain, 20.4% had moderate pain and none had mild or no pain. Difference in VAS score in both groups was statistically insignificant. (p=0.4935) (Table 3)

After 1 hour of drug administration, in paracetamol group, 32.7% of women had severe pain, 57.1% had moderate pain and 10.2% had mild pain. In tramadol group, 52% of women had severe pain, 44.9% had moderate pain and 3.1% had mild pain. Difference was statistically significant (p=0.0020). After 3 hours of drug administration, in paracetamol group, only 37.8% of women had severe pain, 46.9% had moderate pain and 15.3% had mild pain. In tramadol group, 58.2% of women had severe pain, 39.8% had moderate pain and 2.04% had mild pain. Difference was statistically significant. (p=0.0005). (Table 3)

The mean duration of the active phase of first stage of labour in the paracetamol group was 230mins (3hrs50mins) ±50mins and in the tramadol group was 290mins (4hrs50mins) ±58mins. The difference in the mean duration of the active phase of first stage of labour was statistically significant (p<0.0001). (Table 4)

The mean duration of the second stage of labour in the paracetamol group was 40±10mins and in the tramadol group was 44±10.02mins. The difference in the mean duration of second stage of labour was statistically significant. (p=0.0057). (Table 4)

The mean duration of third stage of labour in the paracetamol group was 7±1.20mins and in the tramadol group was 7±1.11mins. The difference in the mean duration

of third stage of labour in the two groups was not statistically significant (p>0.9999). (Table 4)

Total duration of labour from enrolment in study to delivery in the paracetamol group was 278mins (4hrs38mins) ±51.25mins and in the tramadol group was 342mins (5hrs42mins) ±58.16mins. The difference was statistically significant between the two groups (p<0.0001). (Table 4)

Drug delivery interval in the paracetamol group was 271mins (4hrs31mins) ±51.20mins and in the tramadol group was 335mins (5hrs35mins) ±58.16mins. The difference in the two groups was significant (p<0.0001). (Table 4)

Table 3: showing pain intensity by VAS

Time	Pain intensity	Group A		Group B		P value
		N=98*	%	N=98*	%	
Before drug administration	0cm (no pain)	0	0%	0	0%	0.4935 Not sig.
	0.1-3.9cm (mild pain)	0	0%	0	0%	
	4-6.9cm (moderate pain)	24	24.5%	20	20.4%	
	7-10cm (severe pain)	74	75.5%	78	79.6%	
After 1 hour of drug administration	0cm (no pain)	0	0%	0	0%	0.0020 Sig.
	0.1-3.9cm (mild pain)	10	10.2%	3	3.1%	
	4-6.9cm (moderate pain)	56	57.1%	44	44.9%	
	7-10cm (severe pain)	32	32.7%	51	52%	
After 3 hours of drug administration	0cm (no pain)	0	0%	0	0%	0.0005 Sig.
	0.1-3.9cm (mild pain)	15	15.3%	2	2.04%	
	4-6.9cm (moderate pain)	46	46.9%	39	39.8%	
	7-10cm (severe pain)	37	37.8%	57	58.2%	

**Two patients were excluded from the calculation as they underwent LSCS in Group A*
**Two patients were excluded from the calculation as they underwent LSCS in Group B*

Table 4: Showing mean duration of labour

Stage of labour	Group A (n = 98)		Group B (n = 98)		P value
	Mean	SD	Mean	SD	
First stage	230mins (3hrs 50mins)	±50mins	290mins (4hrs 50mins)	±58mins	<0.0001
Second stage	40mins	±10mins	44mins	±10.02mins	0.0057
Third stage	7mins	±1.20mins	7mins	±1.11mins	>0.9999
Total delivery interval	278mins (4hrs 38mins)	±51.25mins	342mins (5hrs 42mins)	±58.16mins	<0.0001
Injection delivery interval	271mins (4hrs 31mins)	±51.20mins	335mins (5hrs 35mins)	±58.16mins	<0.0001

90% women in the paracetamol group and 88% in the tramadol group had spontaneous vaginal delivery. 2% women in both paracetamol group and tramadol group had to undergo LSCS. There were 8 instrumental deliveries in paracetamol group and 10 instrumental deliveries in tramadol group. No statistically significant difference in the mode of delivery was found between the two groups.

Majority of babies had birth weight in between 2.5 to 3.5kg, 87% in paracetamol group and 85% in tramadol group. (table 1)

Apgar score readings at 1min were 7, 8 & 9 scores, in 91% of babies in paracetamol group and 88% in tramadol group. 9% of babies in paracetamol group and 12% of the babies in tramadol group had Apgar score 6 and below at 1 min. At 5mins Apgar score readings were 7, 8 & 9 in 95% in paracetamol group and 96% in tramadol group. There was 1 NICU admissions in tramadol group. The mean Apgar score of neonates in the paracetamol group at 1 min was 7.51±0.77 and at 5 min was 8.75±0.58. The mean Apgar score of the neonates in the tramadol group at 1 min was 7.52±0.80and at 5 min was 8.65±0.66. The difference was statistically insignificant. (p=0.9283, 0.2494). (Table 5)

Table 5: Showing mean Apgar score

Group	Apgar score				P value	
	1min		5min		1min	5min
	Mean	SD	Mean	SD		
Group A (n = 100)	7.51	±0.77	8.75	±0.58	0.9283	0.2494
Group B (n = 100)	7.52	±0.80	8.65	±0.66		

In the paracetamol group, 5% of the cases had nausea, 2% had vomiting and 5% of cases had PPH as their complication. In tramadol group, 9% of women had nausea, 5% had vomiting and another 3% of the patients had PPH. Nausea was the most common side effect seen in the tramadol group (6.4%) followed by vomiting (4.3%). No women in the paracetamol had respiratory depression and foetal tachycardia/bradycardia (table 6).

Table 6: Showing maternal complications

Maternal complications	Group A		Group A		Total	
	Number	%	Number	%	Number	%
None	88	88%	83	83%	171	85.5%
Nausea	5	5%	9	9%	14	7%
Vomiting	2	2%	5	5%	7	3.5%
PPH	5	5%	3	3%	8	4%

4. Discussion

In the present study we found that, paracetamol group had a significant decrease in pain intensity, after 1 and 3hours of intravenous paracetamol administration, about 72.5%, as compared to intramuscular tramadol group about 61.5%. VAS reached the lowest value after 1hour of drug administration in both groups. There was no further change in the mean VAS after 3hours in Tramadol group *(6.8 to 6.6)*; conversely there was further decrease in mean VAS in Paracetamol group after 3hours *(6.0 to 5.6)*. This might be explained by the fact that peak analgesic effect of paracetamol is seen at 1hour, and effect lasts for 4 to 6hours, while for intramuscular tramadol, onset is within 10 min, and action lasts for 2-3 hours.

Our results were quite similar to studies conducted by ***Meenakshi Lallar et al*** (11) ***and Hema Mohan et al*** (9) who found that paracetamol group had a significant decrease in pain intensity at 1 and 3hours after intravenous paracetamol administration as compared to intramuscular tramadol group. Other authors too, there have raised question on analgesic effectiveness of tramadol as it is thought that its perceived analgesic efficacy may be due to at least in part, to its sedative effect rather than true reduction in perceived pain. ***Elbohoty et al*** (8) 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 2hours and was better than pethidine. ***Maryam Khooshideh et al*** (12) on comparing tramadol with pethidine found tramadol to be a weaker analgesic than pethidine. These two studies gives us an interpretation that paracetamol might be a better analgesic than tramadol. On the contrary to our study results, ***Sudha Patil et al*** (2) on studying the efficacy and safety of intramuscular tramadol in 100 primigravidae observed that onset of analgesia with tramadol was 15mins and the analgesic effect lasted for 4 hours. The variation in the length of analgesia among different studies with tramadol can be explained by the fact that CYP 2D6 activity affects tramadol's analgesic activity and enzyme displays genetic polymorphism, some patients being slow metabolisers and others being fast.

There was a statistically significant reduction in the duration of first and second stages of labour after administration of intravenous paracetamol as compared to tramadol. Hence total duration of labour was reduced in patients who received paracetamol as compared to tramadol. ***Meenakshi Lallar et al*** *and* ***Hema Mohan et al*** also observed significant reduction in the duration of 1st, 2nd and 3rd stages of labour after administration of intravenous paracetamol, hence total duration of labour was reduced in patients who received paracetamol as compared to tramadol. Also in the study conducted by ***Jeetinder Kaur Makkar et al*** (10) there was significant decrease in duration of first stage of labour in the paracetamol group as compared to the tramadol group. Previous studies with the use of tramadol have shown varied results with regard to its effect on the duration of labour. ***Maryam Khooshideh et al*** showed a remarkably shorter duration of labour with tramadol as compared to pethidine. ***Keskin et al*** (13) found no statistical difference in the duration of labour between pethidine group and tramadol group (115mins). More studies are required to elucidate the effect of intravenous paracetamol on labour duration, because a decrease in labour duration has multiple potential benefits.

Neonatal outcome was more favourable with paracetamol. Only 1 NICU admission was seen with tramadol. Maternal side effects like nausea and vomiting were observed more in tramadol group. ***Jeetinder Kaur Makkar et al*** 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. The mean Apgar scores at 1 and 5minutes were comparable between the 2 groups, indicating absence of any neonatal adverse effects with the use of either of the 2 drugs.

5. Conclusion

Obstetric analgesia strives at making childbirth a pleasurable and painless event. We can conclude that intravenous paracetamol is simple, safer, cost effective feasible option as labour analgesic in developing countries with low health care resource settings. Paracetamol also shortens the length of labour. Larger studies in this regard could further help establish the efficacy and safety of these drugs.

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