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Research Article

INTRAVENOUS PARACETAMOL INFUSION VERSUS INTRAMUSCULAR TRAMADOL AS AN INTRAPARTUM ANALGESIC

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A B S T R A C T

Aim: To compare intravenous Paracetamol and intramuscular tramadol as labour analgesia and to evaluate the incidence of side effects on mother and fetus of both the drugs. **Material and methods:** It was a prospective, observational and clinically randomized study conducted in the labor room of the dept of Obstetrics and Gynaecology/Govt. medical college Rajindra hospital, Patiala, Punjab. A total of 200 pregnant women were included in study after fulfilling inclusion criteria. these women were divided into 2 groups of 100 each Group A: received a 100ml intravenous infusion containing 1000mg paracetamol single dose over 15min. Group B: received intramuscular tramadol hydrochloride 100mg single dose. Pain intensity of women with both drugs was noted before administration of drug, one hour and three hours after administration of drug using Mc Gills Pain intensity scale.**Result:** No difference in pain intensity is seen before drug administration. After 1 h of drug administration, in paracetamol group, 6.3% women had horrible pain, and 29.5 % had distressing pain, while in tramadol group, 28.6 % women had horrible pain, and 57.1 % had distressing pain. After 3 h of drug administration, in paracetamol group, 23.2 % had distressing pain, while in tramadol group, 46.9 % women had horrible pain, and 32.7 % had distressing pain. Labor duration in paracetamol and tramadol group was 5.2 and 5.6 h, respectively. In paracetamol group, nausea is seen in 6 % and vomiting in 3 %, while in tramadol group, nausea is seen in 8 % and vomiting in 7 %. **Conclusions:** Intravenous paracetamol is more effective labour analgesic with fewer maternal adverse effects and shortens labour as compared to intramuscular tramadol.

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

Giving birth is a painful process. This applies to all social and ethnic groups and has probably been so since mankind walked up right.Nulliparous woman are more likely to experience severe pain than multiparous women.[(1)] Rickford and Regnolds suggest that it is not that women underestimate the pain but tend to overestimate their ability to cope with it.[(2)]

Pain in labor is unpleasant and distressing to the parturient. The relief of pain during childbirth and provision of a dignified birth experience has been of great interest both to the obstetrician and anesthesiologists. Pain management during labor is essential part of good obstetric care. Though this severe pain during labor is not life threatening, it can have neuropsycological consequences. Postnatal depression may be more common when labor analgesia not used.

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Labour pain is a result of many complex interactions, physiological and psychological, excitatory as well as inhibitory. 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 utero-placental blood flow leading to altered fetal homeostasis[(3)(4)] In order to treat labor pain effectively a knowledge of pathways involved is required. Painful impulses from the lower uterine segment and cervix are transmitted via visceral afferent nerve fibers which accompany sympathetic nerve fibers and enter the spinal cord at the tenth, eleventh, twelfth thoracic and first lumber spinal segments. Somatic sensory impulses from vagina and perineum are transmitted via pudendal nerves to the second, third and fourth sacral spinal segments. As is typical of visceral pain, the pain of first stage of labor is often referred to the dermatomes supplied by the same spinal cord segments that receive input from the uterus and cervix (T10 to L1). Providing effective and safe analgesia during labor has remained as an ongoing challenge. Advances in the field of labour analgesia have tread a long journey from days of ether and chloroform in 1847 to the present day practice of comprehensive programme of labor pain management using evidence-based medicine.[(5)] [(6)] Obstetric analgesia and

anesthesia have evolved from vague possibility to reality. The non pharmacological techniques of analgesia include emotional support, relaxed birth environment, psycho-somatic preparation, yoga, acupuncture, transcutaneous electrical stimulation (TENS). [7]

Childbirth education, massage, aroma therapy, audiotherapy, and therapeutic use of hot and cold have been promulgated as nonpharmacologic methods to relieve or mitigate the pain and suffering of childbirth.

Techniques that require specialized training or equipment include hydrotherapy, intradermal water injections, biofeedback, acupuncture or acupressure, and hypnosis. Most of these techniques have not been subject to rigorous scientific study; therefore, conclusion about their efficacy are not possible.[7,8,9] The commonly used and more effective are pharamacological technique, which include opiods like pethidine and tramadol, though the regional analgesia is gold standard nowadays and routinely used in modern obstetric anesthesia in developed countries, Also it entails participation of skilled anaesthesiologist, expensive paraphernalia and incessant monitoring amenities that cannot be made routinely accessible. Therefore there is a need of safe and effective analgesic with minimal maternal and fetal side effects. And also, it should be very simple technique to administer. Paracetamol [10] is a centrally acting drug which inhibits prostaglandin synthesis and used intravenously while Tramadol hydrochloride(11) is a centrally acting analgesic opioid used intramuscularly.these are easily to administer and inexpensive. Here comes into picture, the drugs like paracetamol and opoids like tramadol hydrochloride in the field of labor analgesia, especially in a developing countries like ours, where a major chunk of obstetric services is still rendered by midwives, trained nurses and non-specialist doctors at grassroots levels.

MATERIAL AND METHODS

It was a prospective, observational and clinically randomized study conducted in 200 primigravidae in the labor room of the dept of Obstetrics and Gynaecology/Govt. medical college Rajindra hospital, Patiala, Punjab. Inclusion criteria were primigravida women with spontaneous onset of labor with single fetus with vertex presentation in active phase of labor.Active phase of labor consisted of cervical dilatation more than or equal to 3cm, cervical effacement more than or equal to 60%, and good uterine contractions. Women with medical disorders, obstetrics complications, scarred uterus, clinical evidence of cephalopelvic disproportion, and history of allergy to any opoids or hypersensitivity to the drugs were excluded from the study. After taking an informed consent, these women were divided into 2 groups of 100 each Group A: received a 100ml intravenous infusion containing 1000mg paracetamol single dose over 15min. Group B: received intramuscular tramadol hydrochloride 100mg single dose over upper and outer quadrant of gluteal region with 2ml syringe. Pain intensity before administration drug recorded by Mcgill pain intensity scale.

McGILL Scale	Pain intensity
0	No pain
1	Mild pain
2	Discomfort
3	Distressing
4	Horrible
5	Excruciating

Pain intensity of women with both drugs was noted; before drug administration, after 1hr of drug administration, after 3hr of drug administration, Progress of labor and relief of pain was monitored All patients were monitored for side effects. Maternal side effect in form of nausea vomiting respiratory distress and fetal side effect as fetal bradycardia or tachycardia or any postpartum hemorrhage was noted. If at any point during the study there were indications of maternal or fetal distress, the drug under investigation was withdrawn and adjunctive measures to affect the delivery were immediately implemented. Maternal side effect of both drugs was compared statistatically and monitored. Duration of labour was monitored with duration in 1st stage till delivery interval was also monitored. Apgar score of neonate at 1min and 5 min in both paracetamol and tramadol groups was seen. The following parameters were recorded :Gravidity,Duration of active phase of labor, Rate of cervical dilatation ,Duration of first, second and third stages of labor A WHO simplified partograph was plotted for every case to monitor the progress of labor. Type of complications occurring during labor, Route of delivery. Side effects of the drugs on mother and fetus, Immediate postpartum period The collected data was compiled and analysed statistically using Chi square statistics and compared regarding the comparative efficacy, safety and acceptability of the drugs. Software Excel and Statistical Package for Social Sciences (SPSS) was used.

RESULTS

The mean maternal age was 23.2±2.682 years in Group A and 22.68±2.478 years in Group B. There was no statistically significant difference of age distribution between the two groups. Majority of the subjects presented from rural area 54(54%) subjects in group A and 55(55%) subjects in group B. There was no statistically significant difference of demographic distribution between the two groups. Subjects in Group A had the mean period of gestation as 38.7143±1.1151 weeks and in Group B it was 38.8343±1.15447 weeks. There was no statistically significant difference between the two groups in this regard. Mean cervical effacement at the time of administration of the drug in both the groups was 60-70%. In group A mean cervical effacement was 65.20±10.37 and in Group B it was 64.20±10.04. The difference was not statistically significant between the groups. Majority of the 62(65.3%) subjects in group A and 74(75.5%) subjects in group B had distressing pain as per McGills pain intensity scale at the time of administration of drug. Pain was horrible beyond tolerance in 29(30.5%) subjects and 13(13.3%) subjects in group A and group B respectively. Discomfort during labour was observed in 10(10.2%) subjects in group B and only 4(4.2%) subjects in group A. Only one subject in group B had mild pain while none of subjects in group A had mild pain. Majority of subjects 52(54.7%) 1hr after drug administration in group A were found to be in discomfort zone while only 11(11.2%) subjects in group B were observed to be in discomfort according to Mcgill scale pain intensity scale.28(29.5%) subjects in group A were still having distressing pain while 56(57.1%) subjects in group B were having distressing pain. Only 6(6.3%) subjects in group A were in horrible pain while 28(28.6%) subjects in group B were still having horrible pain,1hr after administration of drug. 9(9.5%) subjects in group A and 3(3.1%) subjects in group B were having mild pain 1hr after administration of paracetamol and tramadol respectively. Pain intensity according to Mcgill

scale was again observed after 3hr of administration of drugs. Majority of subjects in paracetamol infusion group A downstepped into discomfort zone 38(40%) and mild pain zone i.e.33(34.7%) subjects respectively while in group B after 3hr of administration of injection tramadol majority of subjects were still having either distressing pain or horrible pain i.e. 32(32.7%) subjects and 46(46.9%) subjects respectively. Compartively only small number of subjects 22(23.2%) and 2(2.1%) in group A were still in distressing and horrible pain respectively while in group B 11(11.2%) subjects had mild pain and 9(9.2%) subjects were in discomfort. P value difference in pain intensity scale in both group was highly significant.(p value 0.000). The mean duration of active phase of first stage of labor in Group A was 259.02 ±33.781 mins and 273.61 ± 33.494 mins in Group B. The duration of active phase of first stage of labor was shorter in Group A with Infusion Paracetamol as compared to Group B with inj tramadol. The difference is statistically significant (pvalue 0.003). .The mean duration of second stage of labour was 47.13±15.364 mins in Group A and 55.20± 19.159 mins in Group B. So the duration of second stage of labour was shorter in group A as compared to group B.The difference was statistically significant between the groups. The mean duration of third stage of labor was 10.91±2.463 min in Group A and11.28± 2.305 mins in Group B. It was observed that the difference was not statistically significant between the two groups. Majority 95(95%) subjects in group A and 98(98%) in group B were delivered vaginally without any aid. LSCS was done for 5(5%) subjects in group A and 2(2%) in Group B. The subjects who underwent LSCS were then eliminated from further observation. The mean injection delivery interval was 306.15±39.259 mins in Group A and 328.89±39.569 mins in Group B. Injection delivery interval was also found to be shorter of group A as compared to group B tramadol.The result was statistically significant ($p<0.001$). In Group A, 6% subjects complained of nausea, 3% developed vomiting, 2% women had fetalbradycardia/tachycardia, no women had PPH or respiratory distress as compared to Group B where 8 % complained of nausea and 7% developed vomiting, 1% developed fetal bradycardia/tachycardia. The incidence of these side effects was not statistically significant between the two groups. In group A, mean APGAR 8.89±0.549 and 8.96±0.315 at 1 and 5 mins respectively. In Group B, mean APGAR 8.96±0.315and 8.96±0.4 and 5 mins respectively. In group A mean birth weight was 2716.1±340.309 and group B it wa2682.25±449.83 The APGAR score and birth weight was not affected and the difference between the two groups was not statistically significant.

Distribution of Subjects According To Pain Intensity of Subjects in Both Groups Using McGILLs Scale

Time	Pain intensity	Group A		Group B		P Value
		NO	%	N	%	
Before Drug Administration	Mild	0	0	1	1%	0.014
	Discomfort	4	4.2%	10	10.2%	
	Distressing	62	65.3%	74	75.5%	
	Horrible	29	30.5%	13	13.3%	
After 1 hr of Drug Administration Drug	Mild	9	9.5%	3	3.1%	0.000 (HS)
	Discomfort	52	54.7%	11	11.2%	
	Distressing	28	29.5%	56	57.1%	
	Horrible	6	6.3%	28	28.6%	
After 3 hr of Drug Administration	Mild	33	34.7%	9	9.2%	0.000 (HS)
	Discomfort	38	40.0%	11	11.2%	
	Distressing	22	23.2%	32	32.7%	
	Horrible	2	2.1%	46	46.9%	

Distribution of Subjects According To Total Mean Duration of Labour

STAGE	GROUP A (N=95)	GROUP B (N=98)
Active phase of first stage	259.02 ±33.781	273.61 ± 33.494
Second stage	47.13±15.364	55.20± 19.159
Third stage	10.91±2.463	11.28± 2.305
Total Duration of Labor	317.0568±39.22733	340.0918±39.57795
P-VALUE	0.000 HS	

(7 subjects were excluded from the observation as they underwent LSCS)

Distribution of Subjects According To Injection Delivery Interval

Injection- Delivery Interval (mins)	Group A (N=95)		Group B (N=98)	
	No.	Percentage	No.	Percentage
200 – 299	42	44.2%	21	21.4%
300 – 399	51	53.7%	71	72.4%
400-500	2	2.1%	6	6.1%
Mean ± S.D.	306.15±39.259		328.89±39.569	
P-VALUE	0.000 Highly SIGNIFICANT			

(7 subjects were excluded from the observation as they underwent LSCS)

Distribution of Subjects According to Maternal Side Effects/ Complications In Relation to the Drugs Administered In Both Groups

Side Effect	GROUP A (N=100)		GROUP B (N=100)		Pvalue
	No. of patients	Percentage	No. of patients	Percentage	
NAUSEA	6	6%	8	8%	0.159
VOMITING	3	3%	7	7%	0.188
Respiratory distress	0	0%	0	0%	1.000
PPH	0	0%	0	0%	1.000
Fetal tachycardia/bradycardia	2	2%	1%	1%	0.107

Distribution of Subjects According To Neonatal Outcome

Neonatal Outcome	Group A (N=100)	Group B (N=100)	p value
APGAR at 1 min	8.89±0.549	8.83±0.667	0.488
APGAR at 5 mins	8.96±0.315	8.96±0.4	1.000
BIRTH WEIGHT	2716.1±340.309	2682.25±449.83	0.549

DISCUSSION

Labour is one of the most painful experiences women encounter. Although the amount of pain and suffering associated with labour and vaginal delivery varies widely among parturients. Few well- designed studies on prevalence, intensity, and quality of labour pain have been performed. Pain associated with uterine contractions should be distinguished from that associated with delivery: for there are important differencesin clinical characteristics, neural pathways and physiological responses. Paracetamol, the mode of analgesic action of which still not been fully elucidated but probably is a centrally acting drug which inhibits prostaglandin synthesis, has intravenous paracetamol as effective analgesic agent which is safe, effective, inexpensive, and requires no special monitoring. However, there are no significant trials regarding paracetamol analgesic effect on labour pain in women if proved to be an effective analgesic agent in labour, paracetamol being inexpensive and simple to administer could be a boon agent of obstetrics analgesia in developing countries.[18]

Tramadol hydrochloride is a centrally acting analgesic opoid. Intramuscular tramadol hydrochloride 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.[10][11][42]

We undertook this study with the aim to compare efficacy and safety of single dose 1,000mg intravenous paracetamol with 100 mg intramuscular tramadol as labour analgesic.

In the study by Lallar M. *et al* (2014) it was concluded that intravenous paracetamol is more effective than intramuscular tramadol. paracetamol also shortens the length of labor has fewer maternal adverse effects than tramadol. fetal outcome of both drugs are favourable. In a similar study by Makkar J.K *et al*(2014), Hema *et al*(2015), Bishnu *et al*(2016) also concluded that intravenous paracetamol is more effective analgesic than intramusclular tramadol with cost effectiveness safety and minimal side effect and it also shortens the length of labor.

CONCLUSION

Findings of the present study we coclude that intravenous paracetamol is more effective labor analgesic than intramuscular tramadol. Intravenous paracetamol also shortens the length of labor and has fewer side effects than tramadol.

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