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Intravenous Paracetamol Infusion Versus Intramuscular Tramadol as an Intrapartum Labour Analgesic

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Abstract

Aim: To compare between intravenous administration of paracetamol and intramuscular tramadol as a labour analgesic. *Methods:* The present study is a prospective randomised study conducted in 150 primigravida women for a period of 7 months. Inclusion criteria were primigravida with full-term pregnancy in the age group 20-30 years with spontaneous onset of labour with single fetus with vertex presentation in active phase of labour. Active phase of labour was described as cervical dilatation more than or equal to 3 cm, cervical effacement more than or equal to 60% and good uterine contractions. The women were randomly distributed in two groups, Paracetamol group A-75 women and Tramadol group B-75 women after taking informed consent. Mc Gills pain intensity scale was used to measure the pain intensity. *Results:* No significant difference was observed before drug administration in the pain intensity. 2.6% women had horrible pain, and 16% had distressing pain in paracetamol group, while in tramadol group, 21.3% women had horrible pain and 60% had distressing pain after 1 hour of drug administration. After 4 hours of drug administration, in paracetamol group, 16% had distressing pain while in tramadol group, 48% had horrible pain and 40% had distressing pain. In paracetamol group, labour duration was 5.0 hours whereas in tramadol group, it was 6.1 hours. In paracetamol group, nausea was seen in 2.0% and vomiting was seen in 1.5% whereas in tramadol group, nausea was seen in 7.0% and vomiting was seen in 4.1%. *Conclusion*: It can be concluded from this study that intravenous administration of paracetamol is simple, feasible and cost effective and more effective labour analgesic when compared to intramuscular tramadol. Paracetamol has a better analgesic activity, shortening of labour duration and very less side effects.

Keywords: Mc Gills Pain Intensity Scale; Paracetamol; Tramadol.

Introduction

The most excruciating pain experienced by women is labour pain. For most women, child birth is allied with very severe pain. Labour pain is a subjective , multi-faceted, complex and physiological phenomenon that varies in intensity among women and is subjected to many social and cultural modifiers. It encompasses both sensory component and the very vital emotional, motivational and cognitive facets. Maternal psychology and course of labour is affected by labour pain causing anxiety, stress and apprehension [1]. Cervical dilatation and uterine muscle wall ischaemia leading to accumulation of lactate causes pain during the first stage of labour. The vagina and perineum form additional sources of pain during the first stage and second stages of the labour. The increased oxygen consumption, respiratory alkalosis, and metabolic acidosis which could lead to decreased oxygen being transferred to the foetus is caused by the associated increase in sympathetic activity. The relief of pain during labour reduces maternal stress and improves maternal and perinatal outcome. Obstetric analgesia and anaesthesia have originated [2] from vague possibility

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to reality. The emotional support, relaxed birth environment, psycho-somatic preparation, yoga, acupuncture, and transcutaneous electrical nerve stimulation (TENS) are resulted from the non-pharmacological techniques of analgesia. The potent analgesic efficacy with negligible side-effects to be used for pain releif is a characteristic of an ideal labour analgesic. In developed countries, opioids like pethidine and tramadol though the regional analgesia is gold standard nowadays and routinely used in modern obstetric anaesthesia are the commonly used and more effective are pharmacological techniques. The combined spinal epidurals, low dose epidurals, patient- controlled intravenous, inhalational, and epidural analgesia are the newer techniques which have revolutionized obstetric anesthesia. But in the developing countries, most of modern obstetric analgesia practices involve participation of expert anesthesiologist [3], continuous monitoring facilities and costly equipment which unfortunately cannot be available in routine obstetric practice where a majority of obstetric services are in the hands of midwives, trained nurses, and non-specialist doctors. In such situations, minimum technicality method is required.

Paracetamol, is a centrally acting drug which inhibits prostaglandin synthesis, which has recently been made available as intravenous preparation. Various studies have proved intravenous paracetamol as effective analgesic agent which is safe, effective, inex- pensive, and requires no special monitoring. However, there are no significant trials regarding paracetamol analgesic effect on labour pain in women [4]. If proved to be an effective analgesic agent in labour , paracetamol being inexpensive and simple to administer could be a boon agent of obstetric analgesia in developing countries. Tramadol hydrochloride is a centrally acting analgesic opioid. 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 [5]. This study aims to compare the efficacy and safety of intravenous paracetamol and intramuscular tramadol as labour analgesic.

Materials and Methods

The present study is a prospective randomised study conducted in 150 primigravida women attending department of obstetrics and gynaecology during the period of April 2016- October 2016.

Inclusion Criteria

Primigravida with full-term pregnancy in the age group 20-30 years with spontaneous onset of labour with single fetus with vertex presentation in active phase of labour. Active phase of labour was described as cervical dilatation more than or equal to 3 cm, cervical effacement more than or equal to 60% and good uterine contractions.

Exclusion Criteria

Women with medical disorders, obstetric complications, scarred uterus, clinical evidence of cephalopelvic disproportion, and history of allergy to any opioid or hypersensitivity to the drugs.

The women were randomly distributed in two groups, Paracetamol group A-75 women and Tramadol group B-75 women after taking informed consent. In paracetamol group, all the women received a 100 ml intravenous infusion containing 1,000 mg of paracetamol single dose over 15 min, and all the women were given tramadol hydrochloride 100 mg intramuscular single dose in upper and outer quadrant of gluteal region with a 2- ml syringe in tramadol group. Mc Gills pain intensity scale was used to measure the pain intensity.

Results

The present study is a prospective randomised study conducted in 150 primigravida women attending department of during the period of 7 months.

Table 2 shows that in group A and in group B, the highest age range in years was 20-25, in which group A had 40 women and group B had 50 women. The

Table 1: Shows Mc Gills pain intensity scale

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

Table 2: Demographic details

Age (in years)	Group A(n=75)	Group B(n=75)	P Value
<20	20	14	
20-25	40	50	
26-30	15	11	0.078
>30	0	0	
Gestational age (weeks)			
35-39	61	59	
40-42	14	16	0.062
Religion			
Hindu	50	52	
Muslim	17	14	
Sikh	8	9	0.128
Christian	0	0	

Table 3: Shows residence, BMI(Kg/m^2) and cervical dilatation during admission.

Residence	Group A(n=75)	Group B(n=75)	P Value
Urban	23	11	
Rural	52	64	0.067
BMI(Kg/m^2)			
Underweight	35	32	
Normal	37	41	0.022
Overweight	3	2	
Obese	0	0	
Cervical dilatation			
2-4 cm	55	55	
5-6 cm	20	20	0.128

Table 4: Mc Gills pain intensity of the women in paracetamol (group A) and tramadol (group B).

Time	Pain Intensity	Group A (n,%)	Group B (n, %)	P value
Before drug administration	Mild	0, 0.0	0,0.0	
	Discomfort	10,13.3	15,20	0.011(NS)
	Distressing	55,73.3	50,66.6	
	Horrible	10,13.3	10,13.3	
After 1 hr of drug administration	Mild	11, 14.6	4,5.3	
	Discomfort	52,69.3	10,13.3	0.000(S)
	Distressing	12,16	45,60	
	Horrible	2,2.6	16,21.3	
After 4 hr of drug administration	Mild	13, 17.3	4,5.3	
	Discomfort	50,66.6	5,6.6	0.000(S)
	Distressing	12,16	30,40	
	Horrible	0,0.0	36,48	

NS- Not significant, S-Significant.

highest gestational age was 35-39 which had 61 women in group A and 59 women in group B. Hindus were the most women selected in both the groups.

Table 3 shows that the intrapartum analgesia was observed highest in rural areas, group A consisted of 52 women and group B consisted of 64 women. Normal BMI was observed in 37 women in group A and in 41 women in group B. Cervical dilatation of 2-4 cm during admission was seen in 55 women in Group A and it was seen in 55 women in Group B.

Table 4 shows that no significant difference was observed before drug administration in the pain intensity. 2.6% women had horrible pain, and 16% had distressing pain in paracetamol group, while in tramadol group, 21.3% women had horrible pain and 60% had distressing pain after 1 hour of drug administration. After 4 hours of drug administration, in paracetamol group, 16% had distressing pain while in tramadol group, 48 % had horrible pain and 40% had distressing pain.

In paracetamol group, labour duration was 5.0 hours whereas in tramadol group, it was 6.1 hours. In paracetamol group, nausea was seen in 2.0% and vomiting was seen in 1.5% whereas in tramadol group, nausea was seen in 7.0% and vomiting was seen in 4.1%.

Discussion

In present study there is no significant difference was observed before drug administration in the pain intensity. 2.6% women had horrible pain, and 16 % had distressing pain in paracetamol group, while in tramadol group, 21.3% women had horrible pain and 60% had distressing pain after 1 hour of drug administration. After 4 hours of drug administration, in paracetamol group,16% had distressing pain while in tramadol group, 48 % had horrible pain and 40% had distressing pain. In paracetamol group, labour duration was 5.0 hours whereas in tramadol group, it was 6.1 hours. In paracetamol group, nausea was seen in 2.0% and vomiting was seen in 1.5% whereas in tramadol group, nausea was seen in 7.0% and vomiting was seen in 4.1% (Table 4).

Many studies have been done to compare intravenous paracetamol infusion and intramuscular tramadol as an intrapartum analgesic. Vijay Zutshi et al [6], evaluated the efficacy of an intravenous infusion of 1000 mg of acetaminophen as an intrapartum analgesic. The present prospective single-centre, single blind, placebo-controlled randomized interventional study was conducted in Department of Obstetrics and Gynaecology in Vardhaman Mahavir Medical College & Safdarjung Hospital over a period of six months from September 2014 to March 2015. After receiving the ethical clearance and written informed consent. The first 200 consecutive parturients fulfilling the inclusion criteria were recruited into the study. Women were then randomised to receive either intravenous 1000 mg (100ml) of acetaminophen (Group A, n=100) or 100 ml normal saline (Group B, n=100). Primary outcome assessed was effectiveness of acetaminophen to provide an adequate amount of analgesia, as measured by a change in Visual Analogue Scale (VAS) pain intensity score at various times after drug administration. Secondary outcomes measured were duration of labour, need for additional rescue analgesia and presence of adverse maternal or foetal effect. The results were that there was pain reduction at 1 and 2 hours in both groups ($p<0.001$). However, it was more significant in the acetaminophen group, especially at 1 hour. Duration of labour was shortened in both the groups, without any maternal and foetal adverse effects. This study concluded that intravenous acetaminophen is an efficacious non- opioid drug for relieving labour pain without any significant maternal and foetal adverse effects.

Lallar Meenakshi et al [7], have done a study to compare intravenous paracetamol and intramuscular tramadol as labour analgesics. This prospective-randomized study conducted in 200 primigravidae in active labour, distributed into two groups of 100 women each with one receiving intravenous 1,000 mg Paracetamol and other 100 mg intramuscular tramadol. Pain intensity is recorded by McGills scale before, one and3 h after drug administration. Perinatal outcome is recorded. The results were that there was no difference in pain intensity is seen before drug administration. After 1 hour of drug administration, in paracetamol group, 4% women had horrible pain, and 29% had distressing pain, while in tramadol group, 30% women had horrible pain, and 60% had distressing pain. After 3 h of drug administration, in paracetamol group, 26 % had distressing pain, while in tramadol group, 51 % women had horrible pain, and 35 % had distressing pain. Labour duration in paracetamol and tramadol group was 4.3 and 5.9 h, respectively. In paracetamol group, nausea is seen in 2.2% and vomiting in 1.1%, while in tramadol group, nausea is seen in 6.4% and vomiting in 4.3%. It is concluded that intravenous paracetamol is more effective labour analgesic with fewer maternal adverse effects and shortens labour as compared to intramuscular tramadol.

Hema Mohan et al [8], the objective of the study was to compare intravenous paracetamol and intramuscular tramadol as labour analgesics. This prospective-randomized study conducted in 200 primigravidae in active labour, distributed into two groups of 100 women each with one receiving intravenous 1,000 mg Paracetamol and other 100 mg intramuscular tramadol. Pain intensity is recorded by McGills scale before, one and 3 h after drug administration. Perinatal outcome is recorded. The results were that no difference in pain intensity is seen before drug administration. After 1 h of drug administration, in paracetamol group, 4% women had horrible pain, and 28 % had distressing pain, while in tramadol group, 30 % women had horrible pain, and 60% had distressing pain. After 3 h of drug administration, in paracetamol group, 26% had distressing pain, while in tramadol group, 50% women had horrible pain, and 36% had distressing pain. Labour duration in paracetamol and tramadol group was 4.6 and 6.0 h, respectively. In paracetamol

group, nausea is seen in 2.2% and vomiting in 1.1%, while in tramadol group, nausea is seen in 6.4 % and vomiting in 4.3%. It is concluded that intravenous paracetamol is more effective labour analgesic with fewer maternal adverse effects and shortens labour as compared to intramuscular tramadol.

Long J et al [9], evaluated the safety and analgesic efficacy of patient controlled intravenous analgesia (PCIA) with tramadol, and to compare its benefits and risks with combined spinal-epidural analgesia (CSEA)+ patient controlled epidural analgesia (PCEA). Eighty American Society of Anesthesiologist (ASA) I-II at term parturients in active labour were randomly divided into 3 groups: the control group (n = 30) received no analgesia; group A (n = 30) received spinal administration with ropivacaine 2.5 mg and fentanyl 5 microg, then with PCEA; group B (n = 20) received 1 mg/kg tramadol loading dose i.v. PCIA with 0.75% tramadol and it included: PCA dose 2 ml, lockout time 10 minutes, background infusion 2 ml/h, total dose no more than 400 mg. The intensity of pain was evaluated using Visual Analogue Scale (VAS). Both group A and B showed good pain relief. VAS pain scores were significantly decreased in group A and B compared with those in the control group ($P < 0.01$). In comparison with group B, the VAS pain scores decreased in group A ($P < 0.05$). The onset times of analgesia in group A were shorter than those in group B ($P < 0.05$). Apgar scores in group B were lower than those in group A ($P < 0.05$). The periods of second stage of labour in group A were longer than those in the control group and group B ($P < 0.05$) [10]. The caesarean delivery rate was significantly higher in the control group (16.7%) than in group A (3.3%) and group B (5.0%), but it did not differ between group A and B. There were no significant differences in vital signs, fetal heart rate, degree of motor block, and uterine contractions among the 3 groups. It was concluded that PCIA with tramadol is now a useful alternative when patients are not candidates for CSEA for labour, or do not want to have a neuraxial block anaesthesia. However, sometimes it may not provide satisfactory analgesic effect.

Conclusion

It can be concluded from this study that intravenous administration of paracetamol is simple, feasible and cost effective and more effective labour analgesic when compared to intramuscular tramadol. Paracetamol has a better analgesic activity, shortening of labour duration and very less side effects.

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