

Original Research Article

Effectiveness of tramadol compared to pentazocine in pain management during labour

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ABSTRACT

Background: Pain and agony during childbirth is quite often unbearable and at times beyond description. Pain relief can help in removing curb due to pain. To determine the efficacy of intramuscular tramadol hydrochloride as an analgesic during labor compared to those of pentazocine.

Methods: This randomized controlled trial conducted at Jinnah post graduate medical center, ward 8 (Gynaecology and obstetrics) between 2nd December 2013 to 1st June 2014 after approval from the ethical committee of the hospital. Pregnant women aged 15 to 45 years, parity ≥ 1 with Gestational age between 37 to 42 weeks with a single fetus were included in this study. The subjects fulfilling inclusion criteria were enrolled after informed consent. Women were allocated randomly to pentazocine or tramadol. Labour pain was assessed immediately by 4-point visual rating scale before, at 30, and 60 minutes after injection of the trial drug and mean score was calculated. The data was analysed using SPSS version 20.

Results: A total of 128 patients were randomized to ether tramadol or pentazocine. The mean age of enrolled participants is 30 ± 7.01 years and 53.1% participants were below 30 years of age. Of 64 patients who received tramadol, 53 (82.8%) had pain relief compared to 39 (60.9%) in patient who received pentazocine ($p=0.005$).

Conclusions: It is concluded from this study that tramadol is more effective in reducing labor pain

Keywords: Pain, Pain relief, Labor, Tramadol, Pentazocine

INTRODUCTION

Pain is an unpleasant feeling occurring during tissue trauma.¹ WHO states that millions of people experience pain without adequate analgesia.² Pain and agony during childbirth is quite often unbearable and at times beyond description. This pain if not adequately controlled can lead to maternal and fetal sequelae because of widespread maternal sympathetic activation that causes increase in

cardiac output, blood pressure, and pulse rate of the mother.³ Effective analgesia prevents the pain induced hyperventilation and hypocapnia which can be severe enough to produce tetany in painful labor. The requirements of a satisfactory analgesic in labor are safety and effective analgesia throughout the painful periods of labor with no unpleasant maternal side effects and no depressant effect on the baby or on the maternal cardiorespiratory system.⁴

Epidural analgesia is the most effective analgesia for women in labour. Unfortunately, an epidural service cannot be made routinely available in most obstetric units in developing countries for reasons of cost and personnel.^{5,6} Most labour suites therefore use systemic opioids for analgesia. They are cheap, simple to use and readily available. Pethidine has become the most commonly used opioids for obstetric analgesia throughout the world despite an uninspiring safety record. Maternal side effects include nausea, vomiting, sedation and respiratory depression and delayed gastric emptying. Pethidine also produces significant respiratory depression of the neonate and behavioural and feeding problems up to six weeks after delivery. All these adverse effects of pethidine have led to the search for an equally potent but safer systemic analgesics. Other opioids have been tried and the two most commonly available in our country are pentazocine and tramadol.⁷

Besides providing analgesia in labor, regional analgesia may facilitate atraumatic vaginal delivery of twins, preterm neonates, and neonates with breech presentation. It also helps control blood pressure in women with preeclampsia by alleviating labor pain, and it blunts the hemodynamic effects of uterine contractions and the associated pain response in patients with other medical complications.⁸

In a study in Nigeria, it was reported that moderate to good pain relief after 60 minutes of drug administration 47.7% and 30.9% the pentazocine and tramadol group respectively. Hence, they concluded that pentazocine is superior to tramadol.⁸ However in a recent study from India reported pain relief in 80% cases of Tramadol group while in 60% in Pentazocine group. Hence, they concluded that tramadol is superior to tramadol.⁹

The different observation from these two studies creates a clinical equipoise. So, to address this clinical equipoise we were conducting a study comparing the efficacy of tramadol and pentazocine in reducing pain during labor so we come to a conclusion which modality should be used for pain relief during labor.

METHODS

Randomized controlled trial conducted in Jinnah post graduate medical center, ward 8 (Gynaecology and obstetrics) between 2nd December 2013 to 1st June 2014. Sample size was calculated using software package WHO for determination of sample size. Sixty-four patients in each group were required to reach 80% power and 5% level of alpha error to detect a 20% reduction in pain.⁹ Total sample size is at least 128 by non-probability consecutive sampling. Pregnant women aged 15 to 45 years, parity ≥ 1 with gestational age between 37 to 42 weeks with a single fetus were included in the study. Women having following conditions were excluded from this study like cephalopelvic disproportion, respiratory disease, chronic hypertension, heart disease, epilepsy, or

psychiatric disorders, patient with uterine scar, multiple presentations, absent membranes, antepartum haemorrhage, and pre-eclampsia

This study was approved from ethical review committee of the institute. Pregnant women fulfilling inclusion criteria were enrolled in this study after taking written informed consent. Women were allocated randomly to pentazocine or tramadol. Randomization codes were placed in sequentially numbered, opaque, sealed envelope. When each woman requested pain relief, the next numbered envelope was opened and the appropriate drug administered by the resident medical officer.

In tramadol group, inj tramadol 100 mg was given by deep intramuscular injection in upper and outer quadrant of gluteal region with 3 ml syringe. While in pentazocine group, inj pentazocine 30 mg was given by deep intramuscular injection in the upper and outer quadrant of gluteal region with 3 ml syringe. Repeat dose of 50 mg tramadol or 15 mg pentazocine was injected intramuscular after 4 hours if needed.

Labour pain was assessed immediately by four-point visual rating scale before, at 30, and 60 minutes after injection of the trial drug and mean score was calculated. A score 0-1 (No pain-mild pain) was considered as pain relief. The data was recorded in predesigned proforma by principal researcher.

Data analysis

Data entry and analysis was done using SPSS version 19. Frequency and percentages were computed for categorical variable like mode of delivery and pain relief. Chi squared test was applied to compare efficacy in both groups taking $p \leq 0.05$ as significant.

Mean and standard deviations was computed for continuous variables like age, gestational age, parity and severity of labour pain.

Effect modifiers like age, gestational age and parity were controlled through stratification by applying chi squared test and $p \leq 0.05$ was considered significant.

RESULTS

A total of 128 patients were enrolled in this study during study period. The mean age of enrolled participants is 30 ± 7.01 years and 53.1% participants were below 30 years of age, the mean gestational age of enrolled participants is 39.59 ± 1.43 weeks and 72.7% participants were below 40 weeks of gestational age, mean parity of enrolled participants is 1.8 ± 0.88 and 75% participants were primiparous and 58 (45.31%) were delivered normally, 36 (28.13%) through C section, 22 (17.19%) through forceps delivery and 12 (9.38%) were delivered through vacuum delivery.

Of 128 patients, 92 (71.9%) had pain relief and 36 (28.1%) continued to have pain (Figure 1).

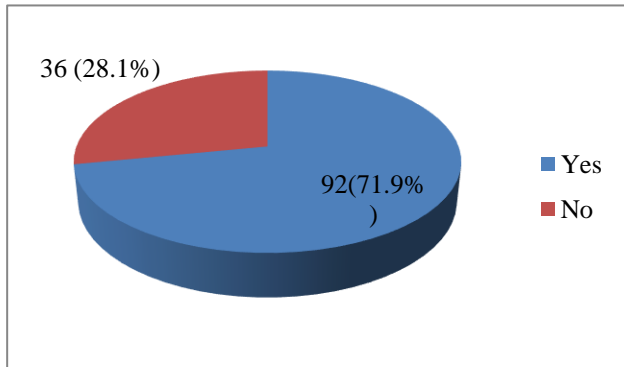


Figure 1: Frequency of pain relief among enrolled participants.

Of 64 patients who received tramadol, 53 (82.8%) had pain relief compared to 39 (60.9%) in patient who received pentazocine (p=0.005). Therefore, tramadol is efficacious compared to pentazocine.

Stratified analysis

Stratified analysis of efficacy of treatment by age, gestational age and parity is summarized in Tables 1-3.

Stratified by age

In patients of age <30 years, the efficacy of tramadol was 82.9% compared to 63.6% who received pentazocine (P=0.064). In patients of age ≥30 years, the efficacy of tramadol was 82.8% compared to 58.1% who received pentazocine (p=0.035)

Stratified by gestational age

In patients of gestational age <40 weeks, the efficacy of tramadol was 77.1% compared to 55.6% who received pentazocine (p=0.024). In patients of gestational age ≥30 weeks, the efficacy of tramadol was 100% compared to 73.7% who received pentazocine (p=0.036)

Stratified by parity

In patients of primipara, the efficacy of tramadol was 78.1% compared to 64% who received pentazocine (p=0.095). In patients of multipara, the efficacy of tramadol was 94.4% compared to 50% who received pentazocine (p=0.006).

Table 1: Stratified analysis of efficacy of treatments arms by age.

Age (Years)		Treatment		P value
		Tramadol	Pentazocine	
<30	Efficacy yes	29 (82.9)	21 (63.6)	0.064
	Efficacy no	6 (17.1)	12 (36.4)	
≥30	Efficacy yes	24 (82.8)	18 (58.1)	0.035
	Efficacy no	5 (17.2)	13 (41.9)	

Table 2: Stratified analysis of efficacy of treatments arms by gestational age.

Gestational age (Weeks)		Treatment		P value
		Tramadol	Pentazocine	
<40	Efficacy yes	37 (77.1)	25 (55.6)	0.024
	Efficacy no	11 (22.9)	20 (44.4)	
≥40	Efficacy yes	16 (100)	14 (73.7)	0.036
	Efficacy no	0	5 (26.3)	

Table 3: Stratified analysis of efficacy of treatments arms by parity.

Parity		Treatment		P value
		Tramadol	Pentazocine	
Primipara	Efficacy yes	36 (78.3)	32 (64)	0.095
	Efficacy no	10 (21.7)	18 (36)	
Multipara	Efficacy yes	17 (94.4)	7 (50)	0.006
	Efficacy no	1 (5.6)	7 (50)	

DISCUSSION

Pain and agony during childbirth is quite often unbearable and at times beyond description. This pain if not adequately controlled can lead to maternal and fetal

sequelae because of widespread maternal sympathetic activation that causes increase in cardiac output, blood pressure, and pulse rate of the mother. Painful labour also reduces utero-placental blood flow by up to 25%. Effective analgesia prevents the pain included

hyperventilation and hypocapnia which can be severe enough to produce tetany in painful labour.¹⁰

In this study we found that tramadol is efficacious compared to pentazocine in pain relief due to labor. Of 64 patients who received tramadol, 53 (82.8%) had pain relief compared to 39 (60.9%) in patient who received pentazocine ($p=0.005$).

In our study, the mean age of patients in tramadol group was 29.34 ± 7.5 years, while in pentazocine group it was 30.66 ± 6.6 years ($p=0.298$). Mean gestational age was 39.55 ± 1.45 weeks in Tramadol and 39.36 ± 1.43 weeks in pentazocine group ($P=0.760$). Mean parity was 1.84 ± 0.94 in tramadol and 1.77 ± 0.831 in pentazocine group ($p=0.621$). Similar findings have been reported by literature.^{11,12}

Kuti et al reported, the mean age of patients in tramadol group was 30.4 ± 4.9 years, while in pentazocine group it was 29.7 ± 5.1 years ($p=0.504$) and mean gestational age was 39.3 ± 1.4 weeks in Tramadol and 39.5 ± 1.6 weeks in pentazocine group ($p=0.504$). These findings are consistent with the findings of our study.

Kavita et al reported that Tramadol group relief pain 80% cases while in Pentazocine group pain relief was observed in only 60% cases. This finding is highly consistent with the findings of our study where tramadol group is more efficacious ($p=0.005$).¹³ Similarly Tripti et al reported 91% pain relief in tramadol group compared to pentazocine ($p=0.002$).¹⁴ Nawani et al observed excellent to average pain relief with tramadol in 80% cases while Sarkar and Mukhopadhyay observed satisfactory pain relief in 73% and average pain relief in 85% cases.^{9,2,15}

Stratified analysis of our study showed that in patients of age <30 years, the efficacy of tramadol was 82.9% compared to 63.6% who received pentazocine ($p=0.064$) and in patients of age ≥ 30 years, the efficacy of tramadol was 82.8% compared to 58.1% who received pentazocine ($p=0.035$), in patients of gestational age <40 weeks, the efficacy of tramadol was 77.1% compared to 55.6% who received pentazocine ($p=0.024$) and in patients of gestational age ≥ 30 weeks, the efficacy of tramadol was 100% compared to 73.7% who received pentazocine ($p=0.036$) and in patients of Primipara, the efficacy of tramadol was 78.1% compared to 64% who received pentazocine ($p=0.095$) and in patients of multipara, the efficacy of tramadol was 94.4% compared to 50% who received pentazocine ($p=0.006$).

There was no significant difference between the two drugs with respect to maternal side effects and outcome of labour. However, pentazocine had more sedative effect than tramadol. Although both drugs are centrally acting, tramadol combines a weak opioid activity with inhibition of nor-epinephrine and serotonin uptake.¹⁵ None of the mothers however fell asleep after drug administration. The mild sedative effect of pentazocine may be an

advantage for women who are noted to be anxious in labour.

CONCLUSION

This study showed that tramadol is safe and effective for the relief of labour pain in our women. Pentazocine, however, is associated with higher incidence of drowsiness.

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Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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