



A Comparison of Tramadol and Pethidine Analgesia on the Duration of Labour

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Abstract

Background: A standard obstetric analgesic should have a good analgesic effect without reducing the intensity of uterine contraction. The present study aimed to evaluate and compare the efficacy of intramuscular tramadol and pethidine on labor pain and duration.

Material and Methods: A total of 170 multigravida women in active labor were randomly assigned to two identical groups, so that 85 pregnant women received pethidine (50mg/2ml) and 85 pregnant women received tramadol (100mg/2ml) intramuscularly.

Results: The labor duration in the tramadol group was shorter than in the pethidine group. In 1st stage of labor, 64.7% of the participants in the tramadol group received the drug for 120±30 minutes, while 67.1% in the pethidine group received the drug for 180±30 minutes. In the 2nd stage, 44.7% of the participants in the tramadol group received the drug for 15±5 minutes, while 51.8% in the pethidine group received the drug for 25±5 minutes. The Visual Analog Scale (VAS) was used before, and 1 and 3 hours after drug administration. The pethidine group obtained a lower VAS mean score compared to those in the tramadol group at 1 hour after drug administration (4 vs 6; $P \leq .001$). Moreover, there was a significant higher level of vomiting and dizziness among women in the pethidine group (29.4% vs 1.2%; $P \leq .001$).

Conclusion: Tramadol appears to lead to a shorter labor duration and cause lower maternal side-effects, although its analgesic efficacy was not as much as pethidine.

Keywords: Labor duration, Pethidine, Randomized trial, Tramadol, VAS score.

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Introduction

Labor is defined as regular uterine contractions that leads to progressive cervical length changes. Therefore, labor diagnosis is normally made in retrospect (1). The labor consists of three stages. The first stage describes the time from the labor diagnosis until the complete cervical dilation (10 cm). This stage is divided into two following phases: (a) the latent phase which is regularly defined as the point at which regular uterine contraction begins and cervical effacement happens. Cervical effacement refers to the process of cervix thinning and stretching out which for most women is usually completed once dilation of 3-4 cm is achieved (2), (b) the active phase which encompasses the time between the ending of the latent phase (3-4 cm cervical dilation) until the cervix is completely dilated (10 cm) (1). The second stage includes the time from complete cervical dilation until the fetus is delivered. This stage can also be divided into two following phases: (a) the passive phase which includes the time between complete cervical dilation and the beginning of involuntary bearing-down contractions (1), (b) the active phase where the mother feels the desire

to push. The third stage refers to the period from the delivery of the baby until the delivery of the placenta and membranes (3).

Pain is known as a key part of the physiology of natural childbirth and regarding the optimal support, a woman is able to cope with normal labor pain using the endorphins naturally produced in the body in response to pain and other stressors (4). Pain caused by uterine contraction can lead to clear physiological changes in oxygen consumption, and cardiopulmonary function. Moreover, it is related to the neuroendocrine regulation of stress response (5). The labor pain as a complicated problem is influenced by several physiological and psychological factors. Besides, the labor pain is intermittent and occurs with uterine contraction (6).

In the first stage of labor, the pain accompanied by uterine contraction as a naturally visceral and cramp-like pain is rooted in the uterus and cervix and is caused by uterine distension and cervical dilation. The impulse of this pain is transmitted by thoracic and lumbar spinal nerves (T10-L1), so it can be perceived in other locations including the abdominal wall, lumbosacral region of the

spine, the crest of the ilium, gluteal region, and thighs (7).

In the second stage of labor, the pain is caused by vaginal and perineal distension and transmitted by the pudendal nerves arising from the S2-S4 nerve roots. The pelvic ligaments stretching is the sure sign of the labor second stage. Pain in the second stage is typified by a combination of visceral pain from uterine contraction, cervical stretches, and somatic pain from vaginal and perineal distension. The mother also experiences a pressure near the rectum area, feels the desire to push, and delivers her baby as the presenting part moves down into the inferior pelvic aperture (8).

Childbirth can be agonizingly painful and the provision of labor pain management is a duty of care and a key factor in having a positive birth experience (9). Decisions on analgesia should be made in the same line and with coordination among obstetrician-gynecologists, anesthesiologists, the patient, and other skilled obstetric care providers (10).

Labor pain management and prevention are complicated problems that might not be effectively tackled by the administration of the best accessible analgesics (11).

Opioids are the most commonly used systemic medications for labor analgesia. Although they do not typically provide complete analgesic effects, they do allow the parturient woman to better tolerate labor pain. In addition, they are available worldwide and easy to administer in most facilities as using these agents does not usually need no specialized equipment or personnel (12).

Opioids are powerful pain-reducing drugs which act through binding to their receptors. Furthermore, they are mainly found in both the central and peripheral nervous systems and the digestive tract as well (13). The efficacy of systemic opioids and the incidence of their side-effects appear to be largely dose-dependent rather than drug dependent (14).

Pethidine is a synthetic and the most widely used opioid in the obstetric setting. Its widespread use is perpetuated due to familiarity with this agent, ease of administration, low cost, and until recently, probable lack of extensive evidence that alternative opioids showed no significant superiority (9).

Pethidine produces its effect mostly through the μ 1- and μ 2-opioid receptors. It is also metabolized in the liver to produce normeperidine, a pharmacologically active metabolite which is a potent respiratory depressant. The norpethidine moves across the placenta and is extracted into the breast milk by passive diffusion, equilibrating between materno-fetal compartments in 6 minutes. Decreased Fetal Heart Rate (FHR) variability occurs within 25-40 minutes after administration and resolves within an hour (15). It gets its peak effect within 30-40 minutes after administration and can be administered again after 3 to 6 hours. The biological half-life of this drug is approximately 23 hours among neonates and this is because drug elimination pathways are immature

among neonates, whilst the biological half-life is merely about 3 hours in adults (12). Maternal adverse effects of this agent are the same as other opioids' adverse effects, i.e. hypoventilation, gastroparesis, nausea, vomiting, sedation, and hypotension (16). Fetal adverse effects consist of reduced muscle activity, hypoxemia, and short-term FHR variability. Neonatal adverse effects include depressed Apgar scores, respiratory distress, low neurobehavioral scores, hypotonia, and suckling damaging effect on lactation (17).

Tramadol Hydrochloride is a codeine synthetic analog and a weak opioid agonist. It has been indicated that this agent has similar analgesic efficacy to pethidine, although it has less maternal sedative effect and less neonatal respiratory depression (18). This agent is also a centrally acting opioid analgesic. In developing countries, Intramuscular (IM) tramadol hydrochloride is a widely utilized labor analgesic, as it is not expensive and there is no need for special monitoring. Moreover, several studies have showed and proved that it is a safe and efficient agent in labor analgesia (19). A 100 mg dose of IM tramadol produces its analgesic effect within 10 minutes and lasts for 2 hours (20). The present study aimed to evaluate and compare the efficacy of intramuscular tramadol and pethidine on labor pain and duration.

Material and Method

Statistical analysis

First, data were entered into Microsoft Excel (Excel version in Microsoft Office 2010 for Windows) and coding took place. Data were then entered into IBM SPSS Statistics for Windows, version 22.0 (IBM Corp., Armonk, N.Y., USA) and analyzed using descriptive (mean, frequency, and percentage) and analytical statistics (t-test, chi-squared, and Analysis of variance). The significance level was considered as $P < 0.05$.

Patient and methods

This is a single-blinded, prospective randomized controlled trial conducted on 170 multigravida women in Sulaimanyah Maternity Hospital from 1 June to 1 December, 2019.

After obtaining written informed consent from all participants, they were randomly assigned to two groups of pethidine ($n=85$) and tramadol ($n=85$).

The pethidine group was administered a 50 mg/2ml dose of pethidine, and the tramadol group was administered a 100 mg/2ml dose of tramadol, both of which received IM injection in the upper outer quadrants of the buttocks.

Inclusion criteria

Inclusion criteria consisted of the followings: (a) cephalic presentation and expectancy for an uncomplicated vaginal birth, (b) low-risk singleton and term pregnancy in active labor (which is defined as showing up at least three regular and painful uterine contractions over 10

minutes along with cervical dilation of 3 cm), and (c) patients who aspire to receive labor analgesia.

Exclusion criteria

Exclusion criteria included the followings: (a) primigravida and grand multiparity, (b) cervical dilation of equal to or greater than 5 cm, (c) existence of any sign of cephalopelvic disproportion, (d) the presence of placental insufficiency or any medical or surgical complications, and (e) using Monoamine Oxidase Inhibitors (MAOIs), opioids, and psychotropics.

Several items including detailed medical history, general physical examination, vital signs (pulse rate, blood pressure, and oxygen saturation) were assessed accurately before, and 1 and 3 hours after drug administration in both groups.

Obstetric abdominal examination including pelvic exam was conducted and blood sample was taken to check essential laboratory tests including Complete Blood Count (CBC), blood group and Rh factor, and viral markers (HBV, HCV).

Labor monitoring and intermittent FHR auscultation were conducted using a partograph and Doppler fetal monitor (Sonicaid), respectively. The pain severity was assessed using the Visual Analogue Scale (VAS) before, and 1 and 3 hours after drug administration in both groups (Figure 1).

All participants were followed up throughout labor till the end of 3rd stage and the following parameters were also recorded:

- Maternal adverse-effects up to the completion of 3rd stage of labor, including nausea and vomiting requiring antiemetic, respiratory depression (respiration rate below 8 bpm), dizziness, and hypoxemia (shown by checking oxygen saturation through pulse oximetry).
- The incidence of fetal distress requiring delivery (presence of meconium-stained liquor).
- Delivery mode
- Apgar score at the 1st minute and the 5th minute after delivery.
- Need for neonatal resuscitation and admission to neonatal intensive care unit.
- Postpartum hemorrhage.

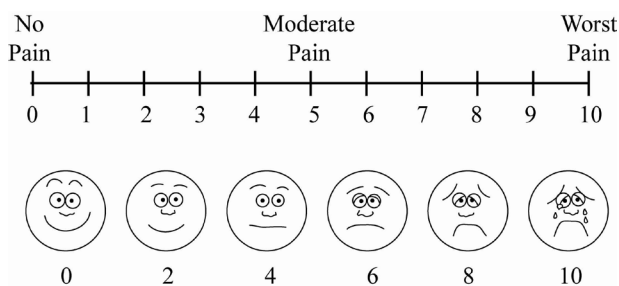


Figure 1. Pain Scale Chart

Results

In the present study, a total of 170 multigravida women in active labor were recruited and then assigned to two groups, so that one group ($n=85$) received pethidine (50 mg/2ml) and another group ($n=85$) received tramadol (100 mg/2ml).

Regarding the demographic Characteristics:

The mean age of participants in the tramadol and the pethidine group was 24.1 ± 4.2 and 23.9 ± 4.4 years, respectively. The mean Gestational Age (GA) of participants in the tramadol and the pethidine group was 38.9 ± 1.01 and 38.9 ± 1.02 weeks, respectively. Regarding the mean cervical dilation in the tramadol and the pethidine group was 3.8 and 3.7 cm, respectively.

Regarding the duration of labor:

In 1st stage of labor, 64.7% of the participants in the tramadol group received the drug for 120 ± 30 minutes, while 67.1% in the pethidine group received the drug for 180 ± 30 minutes. In the 2nd stage, 44.7% of the participants in the tramadol group received the drug for 15 ± 5 minutes, while 51.8% in the pethidine group received the drug for 25 ± 5 minutes. (Table 1).

Pain severity in both group (before, and 1 and 3 hours after drug administration):

The pain severity was measured using the VAS.

Just Before drug administration:

In the tramadol group, 61.2 % of the participants had a VAS score of 8 (moderate to severe pain) and 27.1% had a score of 10 (worst imaginable pain). In the pethidine group, 51.8% of the participants also had the VAS score of 8 and 40% had the score of 10. Accordingly, there was no statistically significant difference in the mean score of pain severity between the two groups before drug administration ($P=0.190$).

At 1 hour after drug administration:

55.3% of the participants in the tramadol group obtained the VAS score of 6 and 28.2% obtained the score of 4. However, in the pethidine group, 58.8% of the participants obtained the VAS score of 4, and 29.4% obtained the score of 2. Based on the above results, there was a statistically significant difference in the mean score of pain severity between the two groups at 1 hour after drug administration ($P=0.001$).

At 3 hours after drug administration:

In the tramadol group, 2.4% of the participants had the VAS score of 0, 36.5% had the score of 2, and 45.9% had the score of 4. In the pethidine group, 20% of the participants obtained the VAS score of 0, 50.6% obtained the score of 2, and 29.4% obtained the score of 4. Based on the above results, there was a statistically significant difference in

the mean score of pain severity between the two groups at 3 hours after drug administration ($p=0.001$). (Table 2)

Maternal side-effects:

Regarding the maternal side-effects, 57.6% of the pregnant women in the tramadol group and 7.1% in the pethidine group complained of nausea. Moreover, 29.4% of the participants in the pethidine group and 1.2% in the tramadol group had vomiting and dizziness (Table 3).

Regarding mode of delivery, meconium-stained liquor, and postpartum hemorrhage:

All participants in both groups had vaginal delivery. Three cases in the tramadol group and only one case in the pethidine group had meconium-stained liquor. Four cases in the tramadol group and only one case in the pethidine group had minor postpartum hemorrhage.

Discussion

In the present study, tramadol was found to be more effective in reducing labor duration than pethidine. In line with the results of our study, Khooshideh et al. (21) found that the labor duration was shorter significantly in the tramadol group compared to the pethidine group in the first (190 vs 140 min; $p<0.0001$) and second labor stage (33 vs 25 min; $p=0.001$). However, Keskin et al. (22) compared the effect of pethidine and tramadol and found that there was no statistically significant difference in labor duration between the two groups. The results of their study are not consistent with the results of our study.

In line with the results of our study, Kushtagi et al. (23) conducted a study titled “A thought for tramadol hydrochloride as labor analgesic” in which primiparous women were assigned to three groups of intervention (Tramadol 50 mg, Tramadol 100 mg, and Meperidine 75 mg) and parturient women, who showed willingness to participate in the study but do not desire to receive analgesics, were recruited to comprise the control group.

Table 1. Relationship between delivery time and treatment

Variable	Treatment N (%)		P Value
	Tramadol	Pethidine	
First stage delivery time (min)			
0-30	0(0)	0(0)	<0.001
30-60	7(8.2)	0(0)	
60-90	12(14.1)	0(0)	
90-120	27(31.8)	3(3.5)	
120-150	28(32.9)	7(8.2)	
150-180	7(8.2)	22(25.9)	
180-210	1(1.2)	35(41.2)	
210-240	3(3.5)	18(21.2)	
Second stage delivery (min)			
0-10	34(40)	14(16.5)	<0.001
10-20	38(44.7)	13(15.3)	
20-30	13(15.3)	44(51.8)	
30-40	0(0)	13(15.3)	
40-50	0(0)	1(1.2)	

Table 2. Relationship between pain score with treatment.

Pain score	Treatment N (%)		P Value
	Tramadol	Pethidine	
Pain score (Before treatment)			
0	0(0)	0(0)	0.190
1	0(0)	0(0)	
2	0(0)	0(0)	
3	0(0)	0(0)	
4	0(0)	0(0)	
5	0(0)	0(0)	
6	10(11.8)	7(8.2)	
7	0(0)	0(0)	
8	52(61.2)	44(51.8)	
9	0(0)	0(0)	
10	23(27.1)	34(40)	
Pain score (After 1hr treatment)			
0	0(0)	0(0)	<0.001
1	0(0)	0(0)	
2	2(2.4)	25(29.4)	
3	0(0)	0(0)	
4	24(28.2)	50(58.8)	
5	0(0)	0(0)	
6	47(55.3)	10(11.8)	
7	0(0)	0(0)	
8	12(14.1)	0(0)	
9	0(0)	0(0)	
10	0(0)	0(0)	
Pain score (After 3hr treatment)			
0	2(2.4)	17(20)	<0.001
1	0(0)	0(0)	
2	31(36.5)	43(50.6)	
3	0(0)	0(0)	
4	39(45.9)	25(29.4)	
5	0(0)	0(0)	
6	12(14.1)	0(0)	
7	1(1.2)	0(0)	
8	0(0)	0(0)	
9	0(0)	0(0)	
10	0(0)	0(0)	

Table 3. Relationship between side effect and treatment.

Side effects	Treatment N (%)		P.V
	Tramadol	Pethidine	
Nausea	49(57.6)	6(7.1)	<0.001
Vomiting	6(7.1)	4(4.7)	
Dizziness	0(0)	3(3.5)	
No symptom	22(25.9)	6(7.1)	
Nausea + Vomiting	4(4.7)	3(3.5)	
Vomiting + Dizziness	1(1.2)	25(29.4)	
Nausea + Vomiting + Dizziness	0(0)	19(22.4)	
Nausea + Dizziness	3(3.5)	19(22.4)	

The mean labor duration was shorter in the tramadol and meperidine groups compared to the control group.

In the present study, both drugs were shown to be effective in reducing the severity of pain, although pethidine was significantly more effective. This result was consistent with the results of the study by Khooshideh et al. (21) in which they found that more than half of parturient women considered the analgesic effect of pethidine as

either good or excellent after drug administration in the first labor stage. They also concluded that pethidine is a better analgesic agent than tramadol in the second stage of labor.

Keskin et al. (22) revealed that there was no significant difference in the analgesic efficacy of pethidine and tramadol at 10 minutes after drug administration. However, they found that the difference was statistically significant at 30 and 60 minutes after drug administration. It was also found that pethidine caused better pain relief than tramadol.

Comparing the maternal side-effects of the two drugs in the present study indicated that about 29.4% of the participants in the pethidine group had vomiting and dizziness, while in the tramadol group, 1.2% had the above complications. This difference was statistically significant ($P < 0.001$).

In line with the results of our study about the maternal side-effects, Khooshideh et al. (21) concluded that the incidence of nausea and vomiting ($P = 0.003$) and dizziness ($P < 0.0001$) was significantly higher in the pethidine group compared to the tramadol group.

In the present study, nausea was most the common side-effect of tramadol (57.6%) and vomiting was also seen in 7.1% of the participants in the tramadol group. In line with this result, Lallar et al. (24) found that nausea was the most common side-effect observed in the tramadol group (6.4 %) followed by vomiting (4.3 %).

Keskin et al. (22) showed that there was a higher incidence of nausea in the tramadol group, although they found that there was no significant difference between the two groups in the incidence of dizziness.

Furthermore, the result of our study revealed that all participants in both groups had vaginal delivery as the mode of delivery.

Conclusion

Based on the findings, tramadol appeared to cause a shorter labor duration. However, the analgesic effect of tramadol was not seemed to be as great as pethidine. Tramadol may be favored over pethidine for analgesia since it caused less maternal side-effects. However, its duration of efficacy was not found to be as long as pethidine. Besides, the findings indicated that both agents can cause a better analgesic effect if they are administered at regular intervals in multiple doses. They also can be good alternatives for each other when one of them is not available. Further studies of each drug with both placebo and intervention groups in the same cervical dilation are recommended in order to do a more accurate assessment of labor pain and duration.

Conflict of Interest Disclosures

There is no conflict of interest to be declared.

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Ethical Approval

Prior to the beginning of the study, ethical approval was obtained from the Scientific and Ethical Committee of Kurdistan Board for Medical Specialties (Ethics No. 1360).

Author Contributions

R Kh: project management/ reviser and editor/ methodology; GF: data analysis/writing/data gathering.

Informed Consent

All participants gave their written informed consent after receiving explanations of the study objective and methodology.

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