Comparative Study between Intravenous Infusion of Pethidine and Intravenous Infusion of Tramadol as an Intrapartum Analgesic in the First Stage of Labor

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Abstract: Background: Labour is a painful condition, considered to be one of the most intense and stressful experiences especially for nulliparous women. Although studies have found a significant rise in pain threshold during labour. It is nonetheless an important goal to provide safe and effective methods of analgesia for women in pain in order, amongst other reasons, to obtain her maximum cooperation. Labour 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. Effective analgesia prevents the pain induced hyperventilation and hypocapnia which can be severe enough to produce tetany in painful labour. Painful labour also reduces uteroplacental blood flow by up to 25%. The requirements of a satisfactory analgesic in labour are safety and effective analgesia throughout the painful periods of labour with no unpleasant maternal side effects and no depressant effect on the baby or on the maternal cardio-respiratory system. **Objective:** To compare the effect of pethidine versus tramadol on the duration of labour in primigravidae women (including active phase of first stage, and second stage of labour), degree of analgesia achieved during labour, maternal **&** fetal side-effects, and early postpartum maternal satisfaction. **Patients and Methods:** This study included 80 pregnant women who were admitted in the first stage of labour at the labour ward of Baab EL Shaarya Hospital, and randomly allocated into two groups, group A and group B; each group consisted of 40women. Each woman in group A received 50 mg pethidine intravenous infusion, while in group B each woman received 100 mg tramadol intravenous infusion. This trial *was* limited exclusively to nulliparous women with uncomplicated pregnancies admitted in spontaneous labour at term presenting in the first stage of labour with adequate pelvis, and vertex presentation. This study excluded any parturient with element of cephalopelvic disproportion or post-dates or fetal distress or ante-partum hemorrhage. **Results:** There was no statistical difference between both groups ($p > 0.05$) as regards demographic data, including age, weight, height BMI, gestational age and fetal weight. In this study, fetal and maternal side effects of pethidine were found as (meconium stained amniotic fluid, vomiting and drowsiness) which were not found in tramadol group, but this difference was statistically non-significant. **Conclusion:** Tramadol has been found to have analogous analgesic efficacy to pethidine but with less sedative effect on the mother, a lower incidence of maternal & fetal side-effects and lack of gastrointestinal side-effects.

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1. Introduction

Pain during childbirth is one of the most excruciating pain experiences that women encountered in their lives. Fear of childbirth has been associated with a longer first and second stage of labour and dissatisfaction with the childbirth experience ***(Saisto et al., 2001)*.** Fear of childbirth has also been implicated in women's requests for caesarean sections and a resultant increased rate of caesarean sections ***(Eriksson et al., 2006).***

Adequate analgesia during labour has a positive influence on the course of labour**.** Most women who deliver in modern obstetric units request some form of pharmacological and non pharmacological pain relief**.** The ideal obstetric analgesic should provide potent analgesic efficacy with minimal maternal and neonatal adverse effects. Epidural analgesia offers the best pain relief for many women in labour. But, when it is contraindicated or woman does not wish to have an epidural analgesia, administration of injectable opioids such as pethidine is a simple and less invasive alternative ***(Khooshideh and Shahriari, 2009).***

Pethidine is one of the most commonly used opioid for labour pain relief since its introduction in the late 1940s. In many Latin American countries, one of its most common obstetric indications is the prescription in patients with a diagnosis of dystocia during the first stage of labour ***(Bricker and Lavender, 2002).***

Pethidine exerts its effect through acting as agonist on opioid receptors. It can be administered intramuscularly or intravenously, due to its poor oral

bioavailability, and is metabolized extensively by the liver then, it is excreted by the kidney ***(Clark et al., 1995)***.

Advantages of Pethidine in labour include maternal relaxation during labour and easy administration by a midwife with no need for a doctor ***(Sosa et al., 2006).*** Many authors hypothesized that there is an indirect effect of pethidine on the uterine contractility, through pain relief and subsequent decrease of adrenaline may finally produce an increase in uterine contractility and decrease length of active phase of labour. Also, pethidine use was associated with changes in the cervical proteases during labour ***(Onur et al., 1989).***

Disadvantages of Pethidine usage in labour includes sickness, vomiting, dizziness, crossing of placenta ***(Sosa et al., 2006),*** increased risk of fetal acidosis at birth, low Apgar scores, neonatal respiratory depression and lower neurobehavioral alertness ***(Hamza et al., 1989)*** such as sleepy baby for a few days and not being interested in feeding. So, breast feeding is less likely to be successful ***(Sosa et al., 2006).***

Tramadol is a synthetic analogue of codeine and a weak opioid agonist, acting centrally by modifying transmission of pain impulse by altering mono amine reuptake mechanisms ***(Khooshideh and Shahriari, 2009).***

Tramadol can be administrated orally, rectally, intra-venously or intramuscularly, and it is principally metabolized in the liver and 90% of it is excreted in urine ***(Lee et al., 1993).*** Transdermal delivery is a new modality of administration of tramadol offering a dual additional opportunity over all its well-known advantages ***(Hussein et al., 2009).***

Tramadol has been found to have analogous analgesic efficacy to pethidine but with less sedative effect on the mother, more shorter duration of labour, a lower incidence of maternal side-effects, less incidence of neonatal respiratory depression ***(Khooshideh and Shahriari, 2009)*** and lack of gastrointestinal side-effects ***(Faisal et al., 2006).***

Aim of the Work

The aim of our study was to evaluate the efficacy and adverse effects of an intravenous infusion of 100 mg of Tramadol during the active phase of labor as compared with an intravenous injection of 50 mg of pethidine hydrochloride as a method for intrapartum analgesia.

2. Patients and Methods

Study design:

A comparative prospective randomized clinical trial.

This study was conducted at the department of obstetrics and gynaecology in Baab Alshaarya University Hospital.

A total of 80 patients in labor presenting for delivery were recruited.

They were selected according to the following Inclusion and Exclusion criteria:

Inclusion criteria:

Age between 18-35 ys old. Low-risk parturients. Spontaneous onset of labor at term (37–42 weeks gestation). Cervical dilatation of 3–6 cm. Single live fetus in cephalic presentation.

Exclusion criteria:

Age <18 or >35 years. Clinical evidence of cephalopelvic disproportion. Any medical disorder during pregnancy. Induction of labor. Use of any other kind of analgesia before recruitment to the study. Scarred uterus. Fetal distress. Previous history of hypersensitivity to either drug.

Intervention

Among the women presenting for labor, those requesting analgesia in the first stage of labor were screened for study eligibility.

Cervical dilatation and demographic data, including age, gestational age, and body mass index (BMI; calculated as weight in kilograms divided by the square of height in meters), were recorded.

After enrollment, each participant was allocated the next available number in a concealed sequence of a computer-generated randomization plan, which determine the drug to be used. The participants were randomly allocated to 1 of 2 groups: in the Tramadol group (n = 40), women received a 100-mg intravenous infusion; in the pethidine group (n = 40), women received an intravenous infusion of 10 mL of normal saline containing 50 mg of pethidine hydrochloride (Pethidine inj. B.P.88, Misr, Cairo, Egypt) over 10 minutes.

Labor was followed up according to the hospital's protocols with artificial rupture of membranes and subsequent application of an oxytocin infusion if there was fewer than 3 contractions in 10 minutes, each lasting less than 40 seconds.

Participants reported pain intensity on a 100-mm VAS, bounded by “no pain” and “the worst pain”, immediately before receiving the study drug and at 15 minutes, 1 hour, 2 hours, 3 hours, and 4 hours after drug administration.

Pain assessment was performed by 1 person (A.E.H.E.), who had no role in patient enrollment and who was blind to the drug administration. Participants who had not delivered within 4 hours and still needed analgesia were given a further infusion as specified by producer, the minimum interval between each administration was 4 hours—whereas those in the

pethidine group were given pethidine as dictated by their case.

Observation of adverse events, both maternal as (dizziness, tachycardia, dyspnea, vomiting, blurred vision, dryness of the mouth, and significant changes in blood pressure [≥ 30 mm Hg systolic or ≥ 15 mm Hg diastolic]), and fetal or neonatal (non-reassuring cardiotocography including fetal tachycardia, low Apgar scores at 1 and 5 minutes, and need for admission to the intensive care unit [ICU]) were recorded. The duration of labor was also calculated.

The primary outcome measure was the efficacy of the drug to supply adequate analgesia, as measured by a change in the VAS pain intensity score at 15 minutes, 1 hour, 2 hours, 3 hours, and 4 hours after drug administration.

Secondary outcome measures included the need for rescue or additional analgesia and the presence of maternal or fetal adverse events during the study.

Statistical Analysis

Data were collected, revised, coded and entered to the Statistical Package for Social Science (SPSS) version 23 and the following were done:

Qualitative data were presented as number and percentages while quantitative data were presented as mean, standard deviations and ranges.

The comparison between two groups with qualitative data were done by using ***Chi-square test*** was used instead of Chi-square test when the expected count in any cell was found less than 5.

The comparison between two independent groups with quantitative data and parametric distribution was done by using ***Independent t-test***.

The confidence interval was set to 95% and the margin of error accepted was set to 5%. So, the p-value was considered ± significant as the following: P > 0.05: Non significant. P < 0.05: Significant. P < 0.01: Highly significant.

3. Results

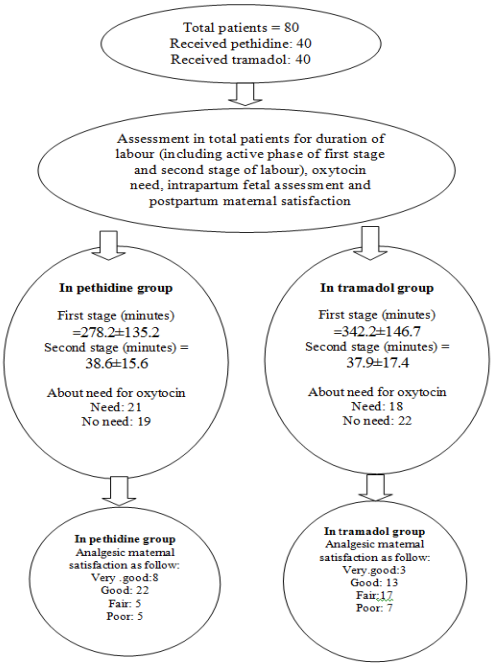

Fig. (1): Summary of results.

Table (1): Comparison between the studied groups as regards demographics data.

	Group A (n=40)				Group B (n=40)			
	Pethidine				Tramdol			
	Mean	±SD	Range		Mean	±SD	Range	
Aactge	23.7	±3.17	18.00	33.00	23.84	±3.43	18.00	34.00
Weight	73.5	±4.25	60.00	81.00	72.60	±5.25	60.00	84.00
Height	161.21	±3.87	155.00	171.00	160.09	±6.45	150.00	170.00
BMI	26.99	±1.85	21.26	31.64	26.53	±1.94	24.97	30.67
GA	37.4	±1.12	37.00	40.00	37.9	±1.96	37.00	40.00
Cervical dilatation	4.12	± 0.74	3.5	5.0	4.24	0.67	3.5	5.00

Table (2): Statistical difference between study groups concerning demographic data & cervical dilatation.

	[Pethidine Injection] (n=40)	[tramdol Injection] (n=40)	t	P	Sig
	Mean±SD	Mean±SD			
Age (Years)	23.7 ± 3.17	23.84±3.43	0.190	0.850	NS
Gestational age (Weeks)	37.4 ± 1.12	37.9± 1.96	1.401	0.165	NS
BMI (Kg/m^2)	26.99 ± 1.85	26.53± 1.94	-1.085	0.281	NS
Cervical dilatation at initiation of analgesia (cm)	4.12 ± 0.74	4.24 ± 0.67	0.760	0.449	NS

Unpaired (student's t) test； NS non-significant

Table (3): Comparison between pethidine and tramadol groups as regards duration of labour.

	Pethidine		Tramadol		t^/$X^{2\#}$	p
	Mean ±SD	Range	Mean ±SD	Range		
• Duration of active phase of first stage (minutes) in normal vaginal delivery	278.2±135.2	20.0-640.0	342.2±146.7	40.0-840.0	2.029^	0.046*
• Duration of second stage (minutes) in normal vaginal delivery	38.6±15.6	10.0-90.0	37.9±17.4	10.0-120.0	-0.189^	0.850
• Total duration in normal vaginal delivery	329.4±160.6	30.0-870.0	377.6±192.5	55.0-960.0	1.216^	0.228
Total duration in caesarean section	375.7±166.2	155.0-560.0	427.5±95.9	300.0-565.0	1.707^	0.092

^Independent t-test, #Chi square test,*Significant

Table (4): Comparison between pethidine and tramadol groups as regards use of oxytocin.

	Pethidine	Tramadol	X2#	p
Oxytocin	21 (52.5%)	18 (45%)	0.450	0.502

#Chi square test

Table (5): Comparison between pethidine and tramadol groups as regards dose-delivery interval (minutes).

	Pethidine (N=40)	Tramadol (N=40)	z^	p
Median (IQR)	150 (90.0-175.0)	165.0 (105.0-210.0)	1.144	0.256
Range	15.0-835.0	15.0-1020		

^Mann Whitney test

Table (6): Comparison between pethidine and tramadol groups as regards dose-delivery interval.

	Pethidine (N=40)	Tramadol (N=40)	$X^{2\#}$	P
• **1 hour**	6 (15.0%)	4 (10.0%)		
• **2 hours**	8 (20.0%)	8 (20.0%)		
• **3 hours**	8 (20.0%)	8 (20.0%)		
• **4 hours**	7 (17.5%)	5 (12.5%)	2.130	0.907
• **5 hours**	2 (5.0%)	5 (12.5%)		
• **6 hours**	4 (10.0%)	5 (12.5%)		
• **> 6 hours**	5 (12.5%)	5 (12.5%)		

^Long rank test

Table (7): Comparison between pethidine and tramadol groups as regards maternal and fetal side effects.

	Pethidine	Tramadol	t^/$X^{2\#}$	P
Maternal side effects.	2 (5.0%)	1 (2.5%)	0.346^	0.556
Fetal side effects	3 (7.5%)	1 (1.7%)	$1.053^{\#}$	0.305

^Independent t-test #Chi square test.

Table (8): Comparison between pethidine and tramadol groups as regards Apgar scores.

	Pethidine		Tramadol		t^/$X^{2\#}$	p
	Mean ±SD	Range	Mean ±SD	Range		
Apgar score at 1min	4.2±0.7	3.0-5.0	4.6±0.8	3.0-7.0	2.380^	**0.020***
Apgar score at 5 min	8.3±0.5	7.0-9.0	8.5±0.4	8.0-9.0	1.975^	0.052

^Independent t-test #Chi square test *Significant

Table (9): Correlation between dose-delivery interval (minutes) and Apgar at 1 & 5 min in pethidine and tramadol groups.

	Pethidine (N=40)		**Tramadol (N=40)**	
	r^	**p**	**r^**	**P**
Apgar at 1min	0.053	0.652	-0.119	0.178
Apgar at 5 min	-0.113	0.198	-0.016	0.963

^Spearman correlation test

Table (10): Comparison between pethidine and tramadol groups as regards Visual analogue scale (VAS).

	Pethidine		**Tramadol**		**z^/$X^{2\#}$**	**p**
	Mean (IQR)	**Range**	**Mean (IQR))**	**Range**		
At Injection	70 (50 – 100)	40 – 100	70 (50 – 100)	30 – 100	-0.346	0.729
After 30 minutes	50 (40 – 80)	20 – 80	70 (45 – 100)	10 – 100	-1.219	0.223
After 60 minutes	40 (10 – 60)	10 – 80	70 (50 – 100)	10 – 100	-3.454	**0.001**
After 120 minutes	80 (30 – 90)	20 – 100	100 (50 – 100)	20 – 100	-2.260	**0.024**

^Mann Whitney test #Chi square test *Significant

Table (11): Comparison between pethidine and tramadol groups as regards maternal satisfaction.

Satisfaction grade	**Pethidine (N=40)**	**Tramadol (N=40)**	**$X^{2\#}$**	**p**
Very good	8 (20.0%)	3 (7.5%)	11.466#	**0.009***
Good	22 (55.0%)	13 (32.5.0%)		
Fair	5 (12.5%)	17 (42.5%)		
Bad	5 (12.5%)	7 (17.5%)		

#Chi square test *Significant

4. Discussion

Pain during childbirth is one of the most excruciating pain experiences that women encountered in their lives ***(Eeriksson et al., 2006).*** Fear of childbirth has been associated with a longer first and second stage of labour and dissatisfaction with the childbirth experience **(*Saisto et al., 2001)*.** Fear of childbirth has also been implicated in women's requests for caesarean sections and a resultant increased rate of caesarean sections ***(Eriksson et al., 2006).***

Adequate analgesia during labour has a positive influence on the course of labour**.** Most women who deliver in modern obstetrics units request some form of pharmacological and non pharmacological pain relief**.** The ideal obstetric analgesic should provide potent analgesic efficacy with minimal maternal and neonatal adverse effects. Epidural analgesia offers the best pain relief for many women in labour. But, when it is contraindicated or woman does not wish to have an epidural analgesia, administration of injectable opioids such as pethidine is a simple and less invasive alternative ***(Khooshideh and Shahriari, 2009).***

Disadvantages of Pethidine usage in labour includes sickness, vomiting, dizziness, crossing of placenta ***(Sosa et al., 2006),*** increased risk of fetal acidosis at birth, low Apgar scores, neonatal respiratory depression and lower neurobehavioral alertness ***(Hamza et al.,1989)*** such as sleepy baby for a few days and not being interested in feeding. So, breast feeding is less likely to be successful (***Sosa et al., 2006).***

Tramadol is a synthetic analogue of codeine and a weak opioid agonist, acting centrally by modifying transmission of pain impulse by altering mono amine reuptake mechanisms ***(Khooshideh and Shahriari, 2009).***

Tramadol can be administrated orally, rectally, intravenously or intramuscularly, and it is principally metabolized in the liver and 90% of it is excreted in urine ***(Lee et al., 1993).*** Transdermal delivery is a new modality of administration of tramadol offering a dual additional opportunity over all its well-known advantages (***Hussein et al., 2009).***

Tramadol has been found to have analogous analgesic efficacy to pethidine but with less sedative effect on the mother, more shorter duration of labour, a lower incidence of maternal side-effects, less incidence of neonatal respiratory depression (***Khooshideh and Shahriari, 2009***) and lack of gastrointestinal side-effects ***(Faisal et al., 2006).***

This study was done to compare the effect 100 mg of tramadol and 50 mg of pethidine with respect to: duration of labour (including active phase of first

stage, and second stage of labour), analgesic efficacy, maternal & fetal side-effects, and early postpartum maternal satisfaction.

This study was a randomized double-blinded controlled clinical trial which included 80 primigravidae women who were admitted for vaginal delivery at the labour ward of Baab El-Sharya University Hospital.

The parturients were randomly allocated into one of two groups: Group A (n = 40), received 50 mg of pethidine intravenous infusion, while group B *(n = 40),* received 100 mg of tramadol intravenous infusion.

On admission, every woman was subjected to complete history to ensure inclusion criteria and to exclude drug allergy, and contraindication of vaginal delivery. Abdominal examination to exclude malpresentation, multiple pregnancy and any evidence of fetal distress and also local examination of cervical dilatation, state of fetal membranes, presenting part, station of fetal head, color of liquor and pelvic adequacy. A partographic representation of labour was done for every patient for assessment of duration of labour. Every patient had described her sensation of pain through a visual analogue scale (VAS) which is a horizontal line, 100 mm in length, anchored by word descriptors at each end where the patient marks on the line the point that she feels representing her perception of her current state. VAS was done at 30, 60 and 120 minutes of pethidine or tramadol administration.

Before delivery, the following were assessed: (1) progress of labour, (2) comparison between the degree of pain that the patient feels before and after pethidine (or tramadol) administration, and (3) maternal adverse effects. However, after delivery, the following were assessed: (1) duration of labour, (2) fetal adverse effects as determined by Apgar score at 1 and 5 minutes, and (3) maternal satisfaction after delivery by using a 4-point descriptive scale of very good, good, fair or bad.

As regards the duration of active phase of the first stage of labour, there was high significant difference between both groups in form of shorter duration in pethidine group (the mean±SD=278.2±135.2 min) than tramadol group (the mean±SD= 342.2±146.7 min) in cases who had vaginal delivery (P < 0.0001).

As regards the duration of second stage, there was no significant difference between pethidine and tramadol groups on the duration of second stage of labour in cases who had vaginal delivery (the mean±SD= 38.6±15.6 min versus 37.9±17.4 min; respectively, p >0.05).

As regards total duration of labour in vaginal delivery, there was no significant difference between pethidine and tramadol groups on total duration of labour in cases who had vaginal delivery (the mean±SD= 326.4±170.6 min versus 374.6±195.5 min; respectively, p>0.05).

This is in agreement with the results reported by ***Husslein et al. (1987)*** *who* performed a randomized controlled trial which compared the efficacy of 100 mg tramadol and 100 mg pethidine in 40 women asking for pain relief during labour. They found that there was a slightly shorter duration of labour in the pethidine group than tramadol group, but this difference was statistically non-significant (p>0.05).

This goes in different with ***Khooshideh and Shahriari (2009)***, who performed a randomized clinical trial on 160 full term parturients that were randomly assigned into two equal groups. One group received 50 mg pethidine intramuscularly and the other group received 100 mg tramadol intramuscularly, they found that the duration of labour was shorter in tramadol group than pethidine group for first stage (the mean±SD=141 ± 29.25min versus 190± 60.52min; respectively, P < 0.01) and also for second stage (the mean±SD= 25± 26.7 min versus 33± 22.56min; respectively, *P*=0.001). The study showed a remarkably shorter duration of labour in the tramadol group (the mean±SD=165± 31.65 min) than pethidine group (the mean±SD= 223± 68.59 min) (p<0.01).

Also, ***Keskin et al. (2003)*** performed a study for comparison between pethidine versus tramadol for pain relief during labour. In this study, 59 full term parturients were randomly assigned to one of two groups. Group 1 received 100 mg pethidine; group 2, 100 mg tramadol, intramuscularly. They found that there was no significant difference in the duration of labour between pethidine group (the mean±SD= 126± 43.31 min) and tramadol group (the mean±SD= 115±32.20 min) (p>0.05).

Also, ***Viegas et al. (1993)*** performed a randomized double-blind clinical trial on 90 pregnant women for comparison between pethidine versus tramadol for pain relief during labour. They found that there was no statistical difference between both group as regards duration of the first and second stages of labour. The mean±SD of duration of labour was 474± 24 min after administration of 100 mg tramadol and 468±30 min after administration of 75 mg IM pethidine (p>0.05).

Comparing dose-delivery interval, there was no significant difference between both groups as regards dose-delivery interval, 29 of the 40 patients in pethidine group and 25 of the 40patients of the tramadol group delivered after 4 hours of analgesic administration.

This is in agreement with the results reported by ***Elbourne et al., (2006)*** that searched the Cochrane Pregnancy and Childbirth Group trials register.

Randomized trials, 16 trials were included, comparing the effects of different opioids administered intramuscularly in labour for women who requested systemic analgesia. The objective of this review was to assess the effects of different opioids administered intramuscularly in labour. They found that there was no evidence of a difference between pethidine and tramadol in terms of interval to delivery, pain relief or operative delivery. However, they found that more adverse effects such as nausea, vomiting and drowsiness appeared with pethidine in comparison to other types of opioids given intramuscular for maternal pain relief on labour.

Concordantly, ***Khooshideh and Shahriari (2009)*** found that most of the patients delivered within 4 hours of analgesic administration. And the duration of labour in only 6 patients in pethidine group was longer than 4 hours.

As regards maternal side effects in the present study, maternal side effects of pethidine group were found as (vomiting in 2 of the 40 and drowsiness in 2 of the 40), which were higher than in tramadol group (vomiting in 1 of the 40), but this difference was statistically non-significant (p>0.05).

This goes in different with ***Fieni et al., (2000), Elbourne et al., (2006), Khooshideh and Shahriari (2009)*** who found that maternal complications were higher in the pethidine group than tramadol group, mainly in the form of nausea and vomiting, and this difference was highly significant (P< 0.0001).

As regards fetal side effects in the present study, fetal side effects of pethidine group were found as (fetal distress in 3 of the 40 and meconium stained amniotic fluid in 4 of the 40), which were higher than tramadol group (fetal distress in 1 of the 40), but this difference was statistically non-significant (p>0.05).

Similarly, ***Khooshideh and Shahriari (2009)*** found that fetal side effects of pethidine group were higher than tramadol group, but this difference was statistically non-significant (p>0.05).

Concordantly, ***Elbourne et al., (2006)*** found that fetal side effects of pethidine group were highly statistically significant than in tramadol group.

Also, this is in agreement to the results reported by, ***Sosa et al. (2006)*** who performed a randomized controlled trial, including a total of 407 patients with term singleton vertex presentations in the active phase of the first stage of labour who were randomized to receive either a placebo or pethidine intravenously in a dose of 100 mg in 50 ml saline solution, to evaluate the association between the use of pethidine during the first stage of labour and the presence, type and timing of acidosis in the newborn at birth. They found that more women received augmentation with oxytocin, had higher prevelance of operative deliveries and presented adverse effects in the pethidine group.

As regards Apgar score in the present study, Apgar score at 1 min of pethidine group was significantly lower than tramadol group. The mean Apgar score at 1 min of pethidine group was 4.2 with standard deviation 0.7 (ranging from 3 to 5), while The mean Apgar score at 1 min of tamadol group was 4.6 with standard deviation 0.8 (ranging from 3 to 7), but there was non-significant difference between both groups as regards Apgar score at 5min The mean Apgar score at 5 min of pethidine group was 8.3 with standard deviation 0.5 (ranging from 7 to 9), while the mean Apgar score at 5min of tramadol group was 8.5 with standard deviation 0.4 (ranging from 8 to 9), Also, there was no correlation between dose-delivery interval and Apgar score at 1 and 5min in both groups.

This is in agreement with the results reported by ***Sosa et al. (2004)*** whose main objective was to evaluate whether the administration of meperidine (pethidine) decreased the duration of labour in women with clinical diagnosis of dystocia in labour, it included 407 women. 202 women were randomly assigned to receive placebo and 205 were randomly assigned to receive meperidine (pethidine), they found that there was a 4-fold increase of mild neonatal depression at 1 minute of life (Apgar score less than 7) in meperidine (pethidine) group compared with the placebo group.

Also, ***Sosa et al. (2006)*** found that there were more cases with clinical depression defined by Apgar score at the first minute of less than seven in the pethidine group than the placebo group (6 events in the pethidine group and 0 in the placebo group).

In contrast to this study, ***Keskin et al. (2003)*** reported that there was no statistically significant difference in mean Apgar scores at 1 and 5 minutes between two groups. Respiratory depression was not observed in any of the parturients and infants, and none of the neonates required opiate antagonists. There was no statistically significant difference in mean Apgar scores at 1 and 5 minutes when two groups were compared. Results of ***Keskinet al. (2003)*** study support the data reported by ***Elbourne et al., (2006)*** who found that Apgar scores were not altered, and respiratory depression requiring resuscitation was not observed with these two drugs.

Also, ***Bredow (1992)*** reported that Apgar scores are not altered and respiratory depression requiring resuscitation is not observed with pethidine and tramadol.

Also, ***Khooshideh and Shahriari (2009),*** found that all neonates (100%) had an Apgar score above 7 at 1 and 5 minutes.

Comparing the analgesic effect of both drugs during labour, it was difficult to assess, since the

perception of pain or tolerance to pain varies among individuals, so that a subjective method was used. Visual analogue scale (VAS) was done at start of study, 30, 60 and 120 minutes after drug administration. The mean VAS pain score at 60 and 120 minutes after treatment when compared to the pretreatment score was found to be reduced (statistically significant) in both groups ($P < 0.001$). There was however, no significant reduction at 30 minutes, when compared to initial VAS; the statistical significant difference in mean VAS between the compared groups was more significant at 60 and 120 minutes with pethidine group than tramadol group.

Also, women who reported very good satisfaction were significantly higher in pethidine group when compared to tramadol group (20%) versus. (7.5%) respectively while women with poor satisfaction were significantly lower in pethidine group than tramadol group (12.5%) versus (17.5%) respectively.

This is in agreement with ***Keskin et al. (2003),*** *who* compared between 100 mg tramadol and 100 mg pethidine as analgesia in labour, and found that there was a significant better pain relief provided with pethidine than tramadol ($P < 0.001$) and also is similar to the results of a study by ***Khooshideh and Shahriari (2009),*** *who* showed that although both pethidine and tramadol could not completely abolish labour pains, they produced comparable results in terms of maternal satisfaction with more than 50% of women rating analgesia as either good or excellent and that administration of 50 mg IV pethidine has an analgesic effect equivalent to that of 100 mg IV tramadol in pain relief in the first stage of labour.

Conclusion

Use of tramadol as an analgesic in labour demonstrated longer duration of the first stage of labour in cases who had vaginal delivery, but there was no significant difference between it and pethidine as regards the duration of second stage of labour in cases who had vaginal delivery, total duration of labour in both cases who had vaginal delivery. Tramadol has been found to have analogous analgesic efficacy to pethidine but with less sedative effect on the mother, a lower incidence of maternal & fetal side-effects and lack of gastrointestinal side-effects.

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