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Tramadol Injection versus Epidural Analgesia in Controlling Labor Pain

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Abstract

Aim of the study: To compare efficacy of tramadol injection as an opioid analgesia versus epidural analgesia on governing labor pain, progress and outcomes (maternal and fetal).

Duration and place of study: Department of Obstetrics and Gynecology Zagazig University from November 2011 to December 2013.

Methodology: One hundred fifty pregnant women primigravida had gestational age between 37 to 41 weeks (confirmed by early ultrasound) with vertex presentation without any risk factors, in established labor (cervical dilation >3 cm with regular uterine contraction) were included in this study divided into two groups, tramadol group (A) and epidural group (B). Subjects of group (A) received 1 mg/kg tramadol intramuscular bolus and 100 mg in 500 ml Ringer lactate at the rate of 8-24 drops/min. and those of group (B) received 0.125% bupivacaine with fentanyl 5 mcg/ml 10-15 mL to be repeated hourly throughout labor and continued until birth. Pain relief was assessed by visual analogue scale of 10 scores ranging from no pain to unbearable pain) before the administration of the drug at 0, 5min., 10min., 15min., 30min., 1 h then every 2 h until full dilatation. Maternal and neonatal out comes were determined.

Results: Total number of patients was one hundred fifty, all were primigravida.The mean age of group A was 22.81 ± 1.89 years and 23.23 ± 1.28 in group B; Mode ofdelivery was spontaneous vaginal in 64 patients (85.3%) in group A and 53 patients (70.6%) in group B Instrumental vaginal delivery in 6 patients (8%) of group A and 13 Patients (17.3%) of group B. Cesarean section in 5 patients (6.6%) of group A and 9 patients12% of group B. At one minute majority of the babies of group A had mean Apgar score 8.7 ± 0. 52 versus 8.65 ± 4.1 at group B. At 5 minute, 9.40 ± 0.33 versus 9.54 ± 0.23. There were no significant differences.In the tramadol group, pain relief was excellent in 13.3%, good in 30.6% and average in 54.6% versus 29.3%, 48% and 22.6% in epidural group. In both the groups there was no significant effect on duration of 1st and 3rd stage of labor but Second stage of labor was prolonged in the epidural group.

Conclusion: Epidural anesthesia and tramadol provided excellent pain relief in majority of the patients. Since, Tramadol administration is easy could be considered as a good alternative to epidural analgesia in lower source settings of the developing nations.

Keywords: Painless labor; Epidural; Tramadol; Analgesia

Introduction

Childbirth is a painful practice for nearly all women. The pain experienced during labor has various physiological and psychosocial Measurements and its strength can vary greatly from one woman to another [1]. Labor pain comprises complex neurobehavioral reactions and offers a personal and distinctive experience to individual women. The cause effect relationship in labor pain does not always correspond to a clinical response; what matters is to understand the pain felt by the pregnant woman and to offer pain release [2]. It has long been known that painful labor produces several adverse changes in maternal physiology and biochemistry; Maternal respiration increases by 75–150% during the first stage of unmodified labor, Hypocarbia, respiratory alkalosis, Increased oxygen consumption, Under-ventilation between contractions, resulting in episodes of haemoglobin desaturation and Compensatory metabolic acidosis, which appears to be transferred readily to the fetus. Maternal anxiety is associated with increased plasma catecholamines and cortisol, and activates the stress response, with release of ACTH and b lipotropin, hence cortisol and b endorphin, though the latter fails to exert much analgesic effect. Increased sympathoadrenal activity may lead to incoordinate uterine action and reduced uteroplacental perfusion [3]. Pain management during labor is an essential part of good obstetric care. Though this severe pain during labor is not life threatening, it can have neuropsychological consequences. Postnatal depression may be more common when labor analgesia is not used. Pain during labor has also been correlated with the development of posttraumatic stress disorder [4]. An ideal analgesic in Obstetrics should have potent opiate like, analgesic efficacy and possess minimal side effects. Psychological methods of pain relief in labor are time consuming, relief unpredictable, inconsistent, and incomplete. Physical methods like transcutaneous electric nerve stimulation, subcutaneous sterile water injection to the lower back, provides limited pain relief [5].

Different anesthetic techniques had been performed to relief labor pain. An epidural anesthesia is a technique performed used to make women more comfortable during labor. The term 'epidural' refers to the space of spine where local anesthetic is injected. The use of this technique allows the patient to be fully awake and participating in all aspects of the birthing process. Epidural anesthesia along with a skilled anesthetist, a faithful obstetrician and a trained midwife can convert the painful labor into a less stressful event [6]. Epidural anesthesia is most frequently used method of pain control. It is reliable and preferred method of anesthesia forever 60% hospitalized women in developed countries. Epidural analgesia is associated with prolonged labor, which

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in turn leads to assisted vaginal birth. A fall in blood pressure may results from the vasodilatation caused by blocking of sympathetic tone to peripheral blood vessels. This hypotension is usually short lived, but may cause a fetal bradycardia due to redirection of maternal blood away from the uterus [7]. However, there may be situations where either it is not available or it is not feasible. Parenteral opioids, thus, are still popular for pain relief in labor in many countries throughout the world. Tramadol is a synthetic analogue of codeine and is a centrally actingagent. It has a relatively low affinity for opiate receptors. Studies have shown that tramadol is an effective analgesic without the maternal and neonatal respiratory depression common to other opioids and it does not delay gastric emptying [8]. Tramadol can be used as labor with minimum cost and less training as compared to the proven epidural analgesia that requires trained staff and equipment and has higher cost. It also avoids the side effects associated with epidural analgesia like fetal heart rate changes, urinary retention, delayed pushing, and a prolonged second stage of labor [9]. The aim of this study is to compare the efficacy, safety and adverse effects of tramadol versus the epidural analgesia in pain relief, mode of delivery and neonatal outcome.

Patients and Methods

This prospective randomized comparative study was conducted in the labor ward of the Obstetrics and Gynecology department, Zagazig University. The study protocol was approved by the Ethics Committee of the Zagazig University Hospitals.One hundred fifty primigravida women with 37-41 weeks of pregnancy were selected. They were in established active stage of labor (uterine contraction 3per 10 minutes, lasting for 30 to 40 seconds, cervical dilation more than 3 cm and up to 5 cm and cervical effacement more than or equal to 60%) with singleton fetus presenting by vertex and agreeable for analgesia. Women with mal presentations, multiple pregnancy, cephalopelvic disproportion, previous cesarean section, antepartum hemorrhage, any medical complications (diabetes, asthma, pulmonary hypertension, hypertensive disorders of pregnancy, laboratory contraindications to epidural catheter insertion or history of allergy to any opioid or hypersensitivity to drug) were excluded from the study. All enrolled women provided written informed consent for participation. Women were allocated to one of two groups using a computer-generated randomization table. Group A (tramadol group) received tramadol 1 mg/kg intramuscularly as a bolus dose in beginning, then 100 mg in 500 ml bolus Ringer's lactate drip at the rate of 8-24 drops/min. Group B (epidural group) received Epidural – 0.125% bupivacaine with fentanyl 5 mcg. Epidural analgesia is adjusted to least analgesic dose (10-15 ml/hr)then top up doses was given according to 2 segment regression and continued till birth. 500 ml of Ringer's lactate solution was given to every parturient in group B before they were subjected to epidural analgesia to diminish the incidence of maternal hypotension and fetal heart rate troubles. Under complete aseptic condition; 18 gauge epidural needle was placed in L2/3 or L3/4 interspace by midline approach. Epidural space was recognized by loss of resistance technique using air or drip drop technique using normal saline, in sitting position at the end of the procedure, epidural catheter was fixed with adhesive plaster at back. Epidural analgesia is adjusted to least analgesic dose (10-15 ml/hr) and increased or decreased according to patient need as assessed by VAS score and also according to progress in laborby Patient controlled epidural analgesia (PCEA) most common or programmed infusion pump [10]. Injections into the epidural space were evaded during contractions and were given in between contractions to avoid the risk of increased spread. Pain was assessed by visual analogue scale (VAS 0- 10) with 0 representing no pain and 10 as the worst pain .VAS graded into (0-4 mild, 4-6 moderate, 7-10 severe pain). Assessment was done before and after the administration of the drug and till full dilatation at (0) then after 5, 10, 15, 30 minutes then at 1 h, 2 h, and 4 h. Routine intraoperative monitors were applied and all the participants were haemodynamically observed prior to the conduct of analgesia and every 5 minutes following injection, non-invasive blood pressure (NIBP), five leads electrocardiogram (ECG), pulse oximetry, blood pressure, heart rate, oxygen saturation and respiratory rate. Maternal hypotension was defined as a systolic blood pressure <90-100 mmhg, fetal wellbeing was monitored by cardiotochography (CTG). Side effects like sedation, vomiting, drowsiness, tachycardia, and fetal distress were noted following the administration of the drug. Maternal sedation was assessed [11].

Intrapartum monitoring was done according to the standard labor ward protocol using the partogram. The time interval between drug administration and delivery was recorded. Labor progress, mode of delivery and side effects of analgesia either maternal or fetal were recorded. Neonatal evaluation was done by the neonatologist who was informed about the type of analgesia given to the mother using APGAR score. Naloxone usage for any presumed opioid induced respiratory depression was recorded. Sample size was calculated based on a pilot study. Statistical analysis of the data was done using SPSS12.0. Results were expressed as mean ± standard deviation (SD). Qualitative analysis was done using Student's *t*-test. For quantitative analysis Chi-square test was used. Nonparametric data were comparedwith Mann-Whitney *U* test. A *P* value of <0.05 was considered significant.

Results

150 women in advanced labor in the duration from November 2011 to December 2013 in Department of Obstetrics and Gynecology Zagazig University hospital were divided into 2 equal groups. All 150 parturients enrolled completed the study. No technical difficulty or inadvertent dural puncture was encountered in the Epidural group. All women who participate were primigravida. Maternal characteristics like age, height, weight, gestational age and cervical dilatation at initiation of analgesia were mentioned in (Table 1). No significant differences between both groups. Table 2 represented maternal haemodynamic changes and side effects of both types of analgesia. There were no statistical differences in both groups as regarding to Mean Pulse Rate and Mean respiratory Rate as p value was >0.05, but the incidence of

characteristics	characteristics Tramadol Group (A) Number (75)	Epidural Group (B) Number (75)	P value
Age (mean ± SD)	22.81 ± 1.89	23.23 ± 1.28	0.6 11
Height cm (mean ± SD)	163.05 ± 5.30	161.04 ± 6.35	0.5 07
Weight kg (mean ± SD)	67.93 ± 5.33	67.80 ± 5.45	0.832
Gestational age weeks (mean ± SD)	38.82 ± 1.54	39.13 ± 1.11	0.212
Cervical dilatation at initiation of analgesia cm (mean ± SD)	4.11 ± 0.251	3.62 ± 0.513	0.130

Table 1: Demographic characteristics (mean ± SD).

Characteristics	Tramadol Group (A) Number(75)	Group (B) Number (75)	P value
Mean Pulse Rate ± SD	80.2 ± 4.7	8o.5 ± 3.9	>0.05 NS
Mean systolic blood pressure ± SD	120.5 ± 4.3	100 ± 5.4	<0.05 S
Mean Respiratory Rate ± SD	18.6 ± 2.2	19.1 ± 1.2	>0.05 NS
Drowsiness (N%)	4 5.3%	3 4.2%	>0.05 NS
Headache	5 6.6%	34 45.3%	<0.05 S
Nausea/ vomiting (N%)	7 9.3%	2 2.6%	<0.05 S
Urine retention	0 0%	7 9%	<0.05 S

Table 2: Maternal haemodynamic changes and side effects of studied analgesia, number of patients (%).

Type of analgesia	Time in (min)						
	0	5	10	15	30	60	2 hour
Group (A) Tramadol (mean ± SD)	86.3 ± 14.2	53.3 ± 12.7	50.4 ± 32.7	46.6 ± 15.8	39.1 ± 19.5	40.1 ± 18.5	28.1 ± 24.5
Group (B) epidural (mean ± SD)	85.2 ± 13.1	31.7 ± 11.7	24.9 ± 9.7	16.6 ± 6.8	22.1 ± 7.1	10.1 ± 3	9.1 ± 6.35
P value	>0.05	<0.01	<0.05	<0.05	<0.05	<0.01	<0.05

Table 3: VAS scores before and after analgesia (mean ± SD).

N Type of analgesia	Grades of pain									
	No pain (0)		mild pain (1)		Moderate pain (2)		sever pain (3)		intolerable pain (4)	
Group (A)tramadol	No	%	No	%	No	%	No	%	No	%
	13	17.3	25	33.3	37	49.3	0	0	0	0
Group (B)epidural	25	33.3	39	52	11	14.6	0	0	0	0
P value	<0.05				NS					

Table 4:Degree of pain relief in studying groups, number of patients (%).

hypotension in the formTransient hypotension in Group (B) was more than in Group (A) with p value <0.05. Most important complication is post epidural puncture headache in group (B) with significant differences between both groups and but no significant difference as regarding drowsiness. Number of patients complained from nausea and vomiting were more in Group (A) with P value <0.05. 7 cases had urine retention in Group (B) and non in Group (A) with P value <0.05. The time atthe end of injection of the analgesia was designated as 0 for the purpose of assessment of pain intensity using VAS at 0 min,5 min, 10 min, 15 min, 30min, 60 min, then every 30 min, until delivery. At the beginning VAS painscore varied from 70 to 95. There were no significant differences within both groups at beginning. After analgesia both groups showed good pain relief. VAS score significantly decrease in Group (B) in comparison to Group (A) at 10, 15, 30 min with p value <0.05 and <0.01 at 5 min, 60 min (Table 3).

Grade 0- Pain relief was in 17.3% women of Group A (tramadol) and 33.3% of Group B (epidural). Grade 1, 2 pain relief also showed significant difference between both groups with P value <0.05. But, in grade 3, 4 no significant differences as no case in any group had sever or intolerable pain (Table 4). There was significant difference in VAS score between both groups in first stage of labor as VAS decreased in Group B with P value <0.05. But, there was no significant difference between them in second and third stage of labor (Table 5). Excellent patient satisfaction was 29.3% women of epidural group and in 13.3% women of tramadol group with P value <0.05 which is statistically significant (Table 6).

There was no significant difference in the period of first and third stage of labor in both studying groups. But, the period of second stage in group (B)was 73 ± 42 which was longer than in Group (A) with P value <0.05 (Table 7). Mode of delivery in Group (A), (85.3%) was spontaneous vaginal and this percentage was more higher than in group (B), (8%) had ventouse delivery, (6.6%) underwent caesarean section and these percentages were lesser than in Group (B) but statistically was not significant (Table 8). Inspite of increase number of non-reassuring fetal heart trace in group (A) more than in Group (A) but difference was insignificant. The mean Apgar score of babies at one minute in group (A) was 8.70, 0. 52 and at 5 minutes was 9.4, 0.33. While mean Apgar score at one minutein group (B) was 8.65, 0.41 and at 5 minutes was 9.54, 0.23 with no significant difference (Table 9).

Group	The first stage	The second stage	The third stage
Group(A) tramadol (mean ± SD)	44.9 ± 19.7	47.1 ± 23.1	30.8 ± 12.1
Group(B) epidural(mean ± SD)	31.4 ± 15.7	35.9 ± 11.1	18.5 ± 6.7
P value	<0.05	>0.05	>0.05

Table 5: VAS score during labor stages in studying groups (mean ± SD).

Type of analgesia	Poor	Average	Good	Excellent
Tramadol	0	41 54.6%	23 30.6%	10 13.3%
Epidural	0	17 22.6%	36 48%	22 29.3%
P value	0	<0.05	<0.05	<0.05

Table 6: Patient satisfaction by labor analgesia, number of patients (%).

Stage of labor	Group (A) Tamadol	Group (B) Epidural	P value
First stage (min)	420 ± 113	433 ± 122	>0.05
Second stage (min)	50.3 ± 16	73 ± 42	<0.05
Third stage (min)	10 ± 4	10 ± 8	>0.05

Table 7: Labor process after analgesia (mean ± SD).

Mode of delivery	Group (B) epidural No. (75)	Group (A) Tamadol No. (75)	P value
Spontaneous vaginal delivery	64 85.3%	53 70.6%	>0.05
Instrumental vaginal delivery	6 8%	13 17.3%	>0.05
Cesarean delivery	5 6.6 5%	9 12%	>0.05

Table 8: Mode of delivery, number of patients (%).

Parameter	Group (B) epidural P value No. (75)	Group (A) Tramadol No. (75)	P value
Mean fetal heart rate (mean ± SD)	145.12 ± 4.1	143.17 ± 5.4	>0.05
Non reassuring fetal (%)	4 5.3%	7 9.3%	>0.05
APGAR Score at 1 min.(mean ± SD)	8.70 ± 0. 52	8.65 ± 0.41	>0.05
APGAR Score at 5 min. (mean ± SD)	9.40 ± 0.33	9.54 ± 0.23	>0.05

Table 9: Neonatal parameters: Mean fetal heart rate, APGAR SCORE AT 1 min and 4 min (mean ± SD) Non reassuring fetal heart trace (%).

Discussion

Epidural administered offer potential analgesics for labor because of their selective effect on perception of pain and sparing of motor, autonomic and other sensory modalities. Drugs which have shorter onset of action were more acceptable. Quick relief from pain is as

important as higher degree of relief of pain. The use of this technique allows the patient to be awake and sharing in all aspects of the birthing process [12]. Despite the acknowledged effectiveness of epidural analgesia and high levels of satisfaction in the majority of women, there are inherent risks and potential sources of dissatisfaction such as inadequate relief, prolongation of labor, need for urinary catheterization and increased risk of instrumental birth [13]. Tramadol hydrochloride a synthetic analogue of codeine has been suggested as equally effective analgesic and is cheaper. It may be preferred over other opioids as it is associated with less sedation [14]. Obstetric analgesia is essential not only for patient's comfort but also for feto-maternal safety as pain associated physiological responses are potentially harmful for the fetus [15].

In group (A), tramadol group; maximum numbers of women (49.3%) were having pain relief of grade-2 type (moderate pain), whereas in group B; epidural group 33.3% had grade 0 (no pain) relief and 14.6% had grade-2 (moderate) relief. Thus the difference in degree of analgesia in the two groups was statistically significant. These results were similar to Jaitley et al. [16]. There is significant prolongation of the 2nd stage of labor in the epidural group (73 ± 42) min. with no significant changes in the duration of 1st and 3rd stage of labor in both groups. Similar results were obtained by Long [17]. In their study 2nd stage were longer, (67 ± 51) min and also the study of Shital [18] who used epidural anesthesia in managing pain during active labor and in spite prolongation of second stage of labor, did not have any adverse effect on the fetal outcome.

In this current study, incidence of cesarean section was 6.6% in tramadol group and 12% in epidural group whereas Desai et al. [19] reported 9.41% cesarean section rate in women of epidural group. Normal delivery occurred in 85.3% of the women in tramadol group and in 70.6% of the women in epidural group and ventouse was applied in 8% of the women in tramadol group and in17.3% of the women in epidural group with no significant differences. Similar results were obtained from study of Pralhad [20] as regard tramadol group who studied intramuscularly tramadol 50 mg versus tramadol 100 mg in primigravida. As regard to fetal outcome, no significant difference in Apgar score of neonates with tramadol or epidural analgesia. Mean Apgar score at 1min intramadol group was (8.70 ± 0.52) and in epidural group it was (8.65 ± 0.41). Similar results were obtained by Long [17]. They reported mean Apgar score at 1min in tramadol group as (8.87 ± 1.55) and in epidural group as (9.50 ± 0.62). Maternal side effects in the form of nausea, vomiting, drowsiness and were less in epidural group as compared to tramadol group. But headache, hypotension and urinary retention were more in epidural than tramadol group The present study is comparable to study of Long [17]. All these side effects were minimal and did not warrant stoppage of the drug. Patient satisfaction was excellentin13.3% of the women of tramadol group and in 29.3% of the women of epidural group with significant difference. In the study reported by Desai et al. [19] and Jain et al. [9] over 90% of the women found epidural to be of great benefit in terms of pain relief. Epidural anesthesia provides excellent pain relief and not associated with fetal compromise in majority of the patients in this study and in a lot of studies and also tramadol hydrochloride injections has maternal and fetal outcomes were close to those of epidural. But, mode of administration of tramadol hydrochloride is simple, cost-effective and practically feasible in any setup. Jain et al. [9] compared intramuscular opioids with epidural analgesia in labor and concluded that, in developing nations where availability of facilities is the main limiting factor, intramuscular opioids can be considered suitable alternatives [9].

Conclusion

Epidural and tramadol provided effective analgesia in majority of the patients. But, as Tramadol is cost-effective**,** has simple mode of administration, and practically possible in any situation. So, it could be considered as a good alternative to epidural analgesia in planned labor in lower source settings of the developing nations.

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