

Tamadol Injection versus Epidural Analgesia in Controlling Labor Pain

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Abstract

Since epidural analgesia was introduced four decades ago for pain relief in labor, controversy has persisted about its effect on the labor process; so, systemic opioid analgesics may be good customary for intrapartum pain control.

Aim of the work

To compare efficacy of tamadol injection as opioid analgesic versus epidural analgesia on governing labor pain, the progress of labor and labor outcomes (maternal and fetal).

Methodology

One hundred and fifty Pregnant women primigravida with 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 and divided into two groups in this study viz. tramadol group (A) and epidural group (B). Subjects of group (A) received 1mg/kg tramadol intramuscularly bolus and 100mg in 500 ml Ringer lactate at the rate of 8–24 drops/min and those of group (B) received Epidural – 0.125% bupivacaine with fentanyl 5 mcg/ml 10–15 ml repeated hourly throughout labour 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 hr and every 2 hr until full dilatation. Maternal and neonatal outcomes were determined.

Results

Total number of patients was one hundred and 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 of delivery was spontaneous vaginal in 64 patients (85.3 %) in group A and 53 patients (70.6 %) in group B while 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 patients (12 %) of group B. At one minute majority of the babies of group A had mean Apgar score 8.70±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 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 & 3rd stage of labor but Second stage of labor was prolonged in the epidural group.

Conclusion

Epidural anaesthesia and tramadol provided excellent pain relief in majority of the patients but, as Tramadol could be considered as an alternative to epidural analgesia in lower source settings of the developing nations as administration is easy.

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, Hypocarbica, 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 in coordinate uterine action and reduced uteroplacental perfusion. [3] Pain management during labor is an essential part of good obstetric care. Though this severe pain during labour is not life threatening, it can have neuropsychological consequences. Postnatal depression may be more common when labour 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, provide limited pain relief. [5] A variety of anaesthesia methods for delivery are used. An epidural anaesthesia is a process used to make a woman more comfortable during labor. The term 'epidural' refers to the space of spine where local anesthetic is provided. It is a local anesthetic, which freezes a person from the abdomen to the feet. The use of this technique allows the patient to be fully awake and participating in all aspects of the birthing process. Epidural anaesthesia along with a skilled anesthetist, a faithful obstetrician and a trained midwife can convert the painful labor into a less stressful event. [6] Epidural anaesthesia is most frequently used method of pain control. It is reliable and preferred method of anaesthesia for over 60% hospitalized women in developed countries. Epidural analgesia is associated with prolonged labor, which in turn leads to assisted vaginal birth. A fall in blood pressure may result 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 acting agent. 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 analgesics 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

hypotension, fetal heart rate changes, impaired motor ability, shivering, urinary retention, delayed pushing, and a prolonged second stage of labor. [9] The purpose of this study was; To evaluate and compare the analgesic efficacy and adverse effects of tramadol to the epidural analgesia in pain relief, mode of delivery and on the Apgar score of fetus.

Patients and Methods

This prospective randomized comparative study was conducted in the labor ward of the Obstetrics & 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 3 per 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 malpresentations, 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 computerized block randomization; group A (tramadol group) received tramadol 1mg/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/ml 10–15 mL and repeated hourly throughout labor until birth. 500ml 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 of fetal heart rate troubles. An 18 gauge epidural needle was placed in L2/3 or L3/4 interspace by midline approach. Epidural space was recognized by the standard technique of loss of resistance with normal saline and negative pressure method. Under aseptic conditions, in sitting position with midline approach. Epidural catheter was fixed with adhesive plaster at back. 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 a 10 cm long visual analogue scale (VAS) with 0 representing no pain and 10 as the worst pain. Pain was then graded into mild (scores of 0–3), moderate (scores of 4–6), and severe (scores of 7–10). Pain was assessed by using VAS before the administration of the drug at 0, 5, 10, 15, 30 minutes then at 1h, 2h, and 4h following drug administration, and at full dilatation. All participants were haemodynamically observed prior to the conduct of analgesia and every 5 minutes following during injection. Blood pressure, pulse rate, peripheral oxygen saturation by pulse oximetry and respiratory rate. Maternal hypotension was defined as a systolic blood pressure < 90–100 mmHg, fetal well being was monitored by cardiotocography (CTG). Side effects like sedation, vomiting, drowsiness, tachycardia, and fetal distress were noted following the administration of the drug. Maternal sedation was assessed on a three-point scale as 0 = alert, 1 = drowsy, and 2 = asleep. 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. Statistical analysis of the data was done using SPSS 12.0. Results were expressed as mean \pm standard deviation (SD). Qualitative analysis was done using Student's *t*-test. For quantitative analysis Chi-square test was used. Nonparametric data were compared with Mann-Whitney *U*- test. A *P* value of <0.05 was considered significant.

Results

Of the total 150 pregnant ladies who requested labor analgesia, 75 women were in the tramadol group and 75 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 in these items. 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 hypotension in Group (B) was more than in Group (A) with *p* value < 0.05 . No significant differences between both groups in occurrence of headache and drowsiness but number of patients complained from nausea and vomiting 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 at the 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, 30 min, 60 min, then very 30 min, until delivery. At the beginning VAS pain score 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 with *P* value <0.05 But, 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 \pm 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. In spite 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 \pm 0.52 and at 5 minutes was 9.40 \pm 0.33. While mean Apgar score at one minute in group (B) was 8.65 \pm 0.41 and at 5 minutes was 9.54 \pm 0.23 with no significant difference Table 9.

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

Table 1: Demographic characteristics (mean \pm SD)

Characteristics	Group (A) Tramadol injection Number (75)	Group (B) Epidural Number (75)	P value
Mean Pulse Rate \pm SD	80.2 \pm 4.7	80.5 \pm 3.9	>0.05 NS
Mean systolic blood pressure \pm SD	120.5 \pm 4.3	100 \pm 5.4	<0.05 S
Mean Respiratory Rate \pm SD	18.6 \pm 2.2	19.1 \pm 1.2	>0.05 NS
Drowsiness (N%)	4 5.3%	3 4.2 %	>0.05 NS
Headache	5 6.6%	4 5.3	>0.05 NS
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	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	85.2±13.1	31.7 ±11.7	24.9±9.7	22.1±7.1	16.6±6.8	10.1±3.5	9.1±6.3
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)

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 painrelief in studying groups, number of patients (%)

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

Table 5: VAS score during labour 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 (A) Tamadol		Group (B) epidural		P-value
	No. (75)		No. (75)		
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 (A) Tamadol No. (75)	Group (B) epidural No. (75)	P-value
Mean fetal heart rate (mean±SD)	145.12±4.1	143.17±5.4	>0.05
Non reassuring fetal heart trace (%)	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

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. [10] 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. [11] Tramadol hydrochloride a synthetic analogue of codeine has been suggested as equally effective analgesic and is cheap. It may be preferred over other opioids as it is associated with less sedation. [12] 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. [13] 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. [14]. 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 & 3rd stage of labor in both groups. Similar results were obtained by Long [15]. In their study 2nd stage was longer, (67±51) min. and also the study of Shital [16] 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. [17] 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 in 17.3 % of the women in epidural group with no significant differences. Similar results were obtained from study of Hiltunen [4] 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 [15]. 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 hypotension and urinary retention were more in epidural than tramadol group. The present study is comparable to study of Long [15]. All these side effects were minimal and did not warrant stoppage of the drug. Patient satisfaction was excellent in 13.3 % of the women of tramadol group and in 29.3% of the women of epidural group with significant difference. In the of study Desai et al. [17] and Jain et al. [9] reported "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 lots 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, tramadol could be considered the choice analgesic in planned labor as an alternative to epidural analgesia in lower resource settings of the developing nations.

References

1. Cambic CR, Wong C (2010) Labor analgesia and obstetric outcome. *Br J Anaesth* 105: i50-i60.
2. Pereira RR, Franco SC, Baldin N (2011) Pain and the protagonism of women in parturition. *Rev Bras Anesthesiol* 61: 376-388.
3. Loo CC, Irestedt L (2000) The benefits of labour analgesia. In: Reynolds F, editor. *Regional Analgesia in Obstetrics: a Millennium Update*. London: Springer 205-217.
4. Hiltunen P, Raudaskoski T, Ebeling H, Moilanen I (2004) Does pain relief during delivery decrease the risk of postnatal depression? *Acta Obstet Gynecol Scand* 83: 257-261.
5. Kushtagi P, Surpaneni N (2012) A thought for tramadol hydrochloride as labor analgesic. *Anesth Essays Res* 6: 147-150.
6. Javed L, Salick A, Farooqi NJ (2005) Epidural analgesia in labour in relation to the rate of instrumental deliveries. *Ann K E Med J11*: 307-310.
7. Agaram R, Douglas MJ, McTaggart RA, Gunka V (2009) Inadequate pain relieve with labor epidurals: a multivariate analysis of associated factors. *Int J Obstet Anesth* 18: 10-14.
8. Claahsen-van der Grinten HL, Verbruggen I, van den Berg PP, Sporken JM, Kollee LA (2005) Different pharmacokinetics of tramadol in mothers treated for labour pain and in their neonates. *Eur J Clin Pharmacol* 61: 523-529.
9. Jain S, Arya VK, Gopalan S, Jain V (2003) Analgesic efficacy of intramuscular opioids versus epidural analgesia in labor. *Int J Gynecol Obstet* 83: 19-27.
10. Camann WR (2003) Conference report: Highlights of the 35th Annual Meeting of the Society for Obstetric Anesthesia and Perinatology, May 14-17, Phoenix, Arizona, US.
11. Sultan P, Murphy C, Halpern S, Carvalho B (2013) The effect of low concentrations versus high concentrations of local anesthetics for labour analgesia on obstetric and anesthetic outcomes: a meta-analysis. *Canadian J Anesth* 60: 840-854.
12. Jain S, Arya VK, Gopalan S, Jain V (2003) Analgesic efficacy of intramuscular opioids versus epidural analgesia in labor. *Int J Gynaecol Obstet* 83: 19-27.
13. Ibrahim SM, ElGazali MS (2009) Uneventful epidural analgesia in a patient with severe thrombocytopenia. *Middle East J Anesthesiol* 20: 291-294.
14. Jaitley A, Singh S, Srivastava U, Nagrath A, Prajapati N, et al. (2011) A Comparison between Epidural and IV Tramadol for Painless Labor and Effect on Perinatal Outcome. *J Obstetrics Gynecol* 61: 42-47.
15. Long J, Yue Y (2003) Patient controlled intravenous analgesia with tramadol for labor pain relief. *Chin Med J (Engl)* 116: 1752-1755.
16. Shital H, Hardik B, Rachit M, Devanshi P (2013) A Study Of Fetomaternal Outcome Of Epidural Analgesia During Labour. *Natl J Med Res* 3: 184-186.
17. Desai P, Patel P, Gupta A (2006) Epidural analgesia in labor. *J Obstet Gynaecol* 56: 417-422.

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