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Research Article

Comparison of parenteral tramadol and epidural ropivacaine for labour analgesia: a prospective clinical study

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ABSTRACT

Background: The pain of childbirth is one of the most severe types of pain that a woman experiences in her lifetime. Adequate analgesia during labour has a positive influence on the course of labour. For labor analgesia several non-pharmacologic and pharmacologic methods are adopted. The objective of the study is to compare parenteral tramadol and epidural ropivacaine with regard to maternal and labour outcome.
Methods: This prospective, comparative, interventional clinical study was conducted at Kasturba Hospital, Daryaganj, Delhi, on the patients admitted in the labour room of the hospital during the period of September 2014 to July 2015. Various parameters of maternal condition and labour outcome in each group were monitored and compared. These included the degree of pain relief and patient satisfaction, duration of 1st and 2nd stage of labour, mode of delivery and duration of third stage and any third stage complication like post-partum haemorrhage (PPH) and retained placenta and side effect profile of both the drugs.
Results: Epidural ropivacaine has significantly better analgesic efficacy and faster onset of action as compared to I/M tramadol and patients in epidural group were significantly better satisfied. Ninety-two percent of patients in tramadol group and eighty eight percent in epidural group underwent normal delivery. Duration of the three stages of labour, complications of third stage and side effect profile in both the groups were comparable.
Conclusions: Maternal outcome in labour analgesia is similar with 100 mg I/M tramadol and epidural ropivacaine. There is no significant difference between duration of labour, rate of LSCS, incidence of instrumental delivery and neonatal outcome in the two modes of analgesia. Analgesic efficacy with epidural ropivacaine seems to be better compared to intramuscular tramadol.

Keywords: Epidural, Ropivacaine, Tramadol, Visual analogue scale

INTRODUCTION

Pain during childbirth is one of the most excruciating pain experienced by women in their lives.[1] Fear of childbirth has been associated with a longer first and second stage of labour and dissatisfaction with the childbirth experience.[2] Most women who deliver in modern obstetric units request for some form of pharmacological or non-pharmacological pain relief. The ideal obstetric analgesic used should be cheap, easy to administer, produce good and reliable relief from pain but not impair consciousness and cooperation. It should have minimal maternal and neonatal adverse. A variety of labour analgesia options are available, including psychoprophylaxis, transcutaneous electrical nerve stimulation (TENS), systemic medication, inhalational techniques, and neuraxial blocks. In addition, other regional techniques such as caudal or para-cervical block are used infrequently.

Ropivacaine in epidural anaesthesia is known to cause less motor blockade and high maternal satisfaction.

Epidural analgesia effectively relieves labour pain and is now chosen by many parturient women. In addition to their analgesic benefits, the physiological benefits of epidural analgesia for the mother and fetus are well-documented.[3-6] Whether epidural analgesia affects labour and delivery is a matter of debate.

Tramadol is a weak opioid which inhibits nor-adrenergic and serotonergic transmission, having analogous analgesic efficacy to other opioids like meperidine but is without much maternal sedation and neonatal respiratory depression. It can be used by various routes such as oral, intramuscular, intravenous and epidural with minimal side effects. It is a potent analgesic which can be given to the labouring patients. Parenteral tramadol is being a less invasive alternative. It can be given by obstetricians themselves.

This study aims to compare the two widely used obstetrical analgesia techniques, parenteral tramadol and epidural ropivacaine with regard to their analgesic effect and maternal and labour outcome.

METHODS

This prospective, comparative, interventional clinical study was conducted at Kasturba hospital, Daryaganj, Delhi, on the patients admitted in labour room of the hospital during the period of September 2014 to July 2015.

All primigravida patients planned for vaginal delivery and in spontaneous active labour with full term singleton pregnancy in vertex presentation were included. Patients with medical disorders like hypertension, diabetes, renal disorder, heart disease, anemia, multiple pregnancy, mal-presentations, previous cesarean and history of allergy to ananesthetic/analgesic agents were excluded. After selecting patients using the above criteria, an informed consent was taken. Complete history and examination of the patient was done. Weight and height of all the patients was measured and patients with weight between 50 to 80 kg and height 140 to 170 cm only were included. All routine antenatal investigations were done. Two groups were made with 50 patients in each group. Patients in group A received 100 mg tramadol intramuscularly in the upper outer quadrant of the buttocks at the onset of active labour. Same dose was repeated after 6 hours, if required. In Group B, 50 patients received lumbar epidural block and were administered 12 to 20 ml of 0.2% ropivacaine (depending upon patient's height) for initial injection through epidural catheter and 6ml of the same concentration was given for top up as and when required.

Following parameters of maternal condition and labour outcome in each group were monitored and compared:-

Degree of pain relief and patient satisfaction

Quality of analgesia using a visual analogue scale (VAS) score from 0-10 with 0 denoting no pain, and 10 indicating worst pain imaginable by the parturient. The VAS score was taken prior to induction/injection and then 1, 5, 10, 20, 30, 60 minutes and hourly thereafter, after placement of the block/injecting tramadol, and maximum analgesia was noted.

Effects on labour and delivery including

Duration of 1st and 2nd stage of labour. P/V and dilation of cervix at the time of administering analgesia and duration of labour from administration of analgesia to full dilatation of cervix and interval from full dilatation of cervix to delivery of the baby was noted.

Mode of delivery

Normal/instrumental/cesarean section.

Effect on the 3rd stage of labour

Active management of third stage was done for all the patients by administering 10 units oxytocin I/M within 1 minute of delivery. Duration of third stage and any third stage complication, like PPH and retained placenta were noted and any intervention required including MRP and measures used to control PPH were noted.

Side effects

Including nausea, vomiting, giddiness, dizziness and any untoward reaction was noted. The data was analyzed using appropriate statistical tests (chi square test, fisher's test, unpaired t-test).

RESULTS

Table 1: Comparison of age group and gestational in patients given I/M tramadol with patients given epidural ropivacaine.

Age (years)	Tramadol group		Epidural ropivacaine group	
	Patients			
	No.	Percent	No.	Percent
<20	1	2%	2	4%
21-25	45	90%	45	90%
26-30	4	8%	3	6%
Gestation age (in weeks)	**Tramadol group**		**Epidural ropivacaine group**	
	Patients			
	No.	**Percent**	**No.**	**Percent**
37-38	18	36%	14	28%
38-39	20	40%	26	52%
39-40	12	24%	10	20%

Mean age of patients in tramadol group was 23.14±4.06 and mean age in epidural group was 22.92±4.21. Difference between age groups and gestational ages was statistically not significant (Table 1).

Patients less than 4 cm were not included in the study. Initial cervical dilation in both the groups was comparable (Table 2).

Table 2: Comparison of cervical dilatation of patients at the time of administration of 1st dose of analgesia.

Cervical dilation at	Tramadol group		Epidural ropivacaine group	
The time of 1st dose	Patients			
	No.	Percent	No.	Percent
4 cm	43	86%	40	80%
5 cm	4	8%	10	20%
6 cm	3	6%	0	0

All patients included in the study had unbearable pain before analgesia and most of them rated it as worst pain they've ever had. All patients labelled the VAS score between 8 to10 before any analgesia was administered. After receiving 100mg I/M tramadol, only 34% patients had a significant fall in VAS scores (VAS ±5). Maximum fall in VAS score was to 2 (2 patients). In 30% of patients, VAS score remained between 8 to 10 after receiving 100 mg I/M tramadol. Mean VAS score in tramadol group after analgesia was 6.3. There was no significant fall in VAS score after tramadol (p =0.186). In the epidural ropivacaine group, 92% patients had a significant fall in VAS score i.e less than or equal to 5. 28% patients had VAS score 0 to 1. In 4% of patients VAS score was 8-10 after giving analgesia.

Mean VAS score after epidural ropivacaine was 3.18. Significant fall in VAS score was observed after the use of epidural ropivacaine (p=0.000). There was significant difference between mean VAS after analgesia between the two groups and significantly better analgesic efficacy was observed with epidural ropivacaine compared to I/M tramadol (Table 3).

Table 3: Analgesic efficacy of I/M tramadol with epidural ropivacaine for patients in active labour using VAS score.

VAS score	Tramadol group after analgesia	Epidural ropivacaine group after analgesia
0-1	0	14
2-3	2	13
4-5	15	19
6-7	18	2
8-10	15	2

Patients were asked subjectively about their satisfaction with the analgesic technique administered to them. 52% patients in tramadol group were fairly satisfied, whereas 34% patients in epidural group had fair satisfaction. 40% patients in tramadol group were poorly satisfied in contrast to only 8% patients in epidural group who had poor satisfaction. Patients in epidural group were significantly better satisfied compared to tramadol group. (Fisher's Exact test p-value=0.000) (Table 4).

Table 4: comparison of the level of satisfaction in patients receiving epidural ropivacaine with I/M tramadol.

	Tramadol group (A)		Epidural group (B)	
Patient satisfaction	Patients			
	No.	%	No.	%
Very good	0	0	15	30
Good	3	6	14	28
Fair	27	52	17	34
Poor	20	40	4	8

Table 5: Comparison of the time of onset of analgesia in patients receiving epidural ropivacaine with I/M tramadol.

Time of onset (min)	Tramadol group (A)	Epidural group (B)
0-5	0	0
6-10	2	9
11-15	7	38
16-20	11	1
21-25	13	0
26-30	2	0
Negligible effect	15	2

Time of onset of analgesia was defined as time interval between introduction of drug and any pain relief felt by the patient. Most of the patients in the tramadol group (48%) had onset of analgesia between 16 to 25 minutes. While in the epidural group, most patients (76%) had an onset between 11 to 15 minutes. Mean time of onset in tramadol group was 20.68±8.14 minutes while in epidural group was 12.82±3.76 minutes. Onset of analgesia with epidural ropivacaine was significantly faster compared to I/M tramadol.

Table 6: Comparison of the mode of delivery in patients given epidural ropivacaine with patients given I/M tramadol.

Mode of delivery	Tramadol group		Epidural ropivacaine group.	
	Patients			
	No.	%	No.	%
NVD	46	92	44	88
LSCS	4	8	5	10
Instrumental	0	0	1 (forceps)	2

In tramadol group, four patients underwent LSCS due to fetal distress. In epidural group, 5 patients underewent LSCS and 1 patient had forceps delivery. Forceps were applied because of 2nd stage fetal distress with poor maternal bearing down efforts. Five patients underwent LSCS due to fetal distress (Table 6).

Table 7: Comparison of duration of 1st stage of labour in patients receiving I/M tramadol with patients receiving epidural ropivacaine.

Duration of 1st stage in min	Tramadol group		Epidural group	
	Patients			
	No.	%	No.	%
60-79	10	21.7	6	13.33
80-109	14	30.43	15	33.33
110-129	14	30.43	12	26.67
130-149	2	4.3	5	11.11
150-169	6	13.04	2	4.44
170-189	0	0	4	8.89
190-209	0	0	0	0
210-229	0	0	0	0
230-249	0	0	0	0
250-269	0	0	1	2.22
Total	46	100	45	100

Only patients undergoing vaginal delivery were included for comparison of duration of the first stage of labour. Thirty eight patients (82.56%) in tramadol group had duration of 1st stage between 80-129 min. Whereas in the epidural group, 33 patients (73.33%) had duration of 1st stage between 80-129 min. Mean duration of 1st stage was 104.36±55.2 min in tramadol group and 115.34±74.82min in epidural group. Difference between the two was statistically not significant (Table 7).

Table 8: Comparison of duration of 2nd stage of labour in patients receiving I/M tramadol with patients receiving epidural ropivacaine.

Duration in minutes	Tramadol group		Epidural group	
	Patients			
	No.	%	No.	%
0-20	27	58.7	20	44.44
21-40	16	34.78	20	44.44
41-60	3	6.5	5	11.11
Total	46	100	45	99.99

Majority of patients in both groups i.e. 43 patients (93.48%) in tramadol group and 40 patients (88.89%) in epidural group had duration of second stage upto 40 min. Mean duration of 2nd stage in tramadol group was 23.94±21.86 and in epidural group was 27.84±24.54. Difference between the mean duration of 2nd stage between the two groups was statistically not significant (Table 8).

All the patients in tramadol group and 44 patients (97.78%) in epidural group had delivery of placenta within 20 minutes. Only one patient in the epidural group had retained placenta when MRP was done. Mean duration of 3rd stage in tramadol group was 8.38±6.52 min and in epidural group was 8.89±8.78min. Difference between the mean in two groups was statistically not significant (Table 9).

Table 9: Comparison of duration of 3rd stage of labour in patients receiving I/M tramadol with patients receiving epidural ropivacaine.

Duration in minutes	Tramadol group		Epidural group	
	Patients			
	No.	%	No.	%
0-10	43	93.33	41	91.11
11-20	3	6.52	3	6.67
21-30	0	0	1	2.22
Total	46	100	45	100

Table 10: Comparison of complications observed in the 3rd stage in patients given I/M tramadol with patients given epidural ropivacaine.

Complication	Tramadol group		Epidural group	
	Patients			
	No.	%	No.	%
Atonic PPH	2	4	2	4
Retained placenta (MRP done)	0	0	1	2
No complication	48	96	47	94

Third stage was actively managed in all patients by administering 10 units oxytocin I/M within 1 min of delivery. In both the groups, two patients each had atonic PPH which was controlled by uterine massage, 20units oxytocin drip and injection metherg in 0.2 mg I/M In epidural group, one patient had retained placenta, for which manual removal of placenta was done. There was no significant difference in the complications observed in 3rd stage in between the two groups (Table 10).

Table 11: Comparison of maternal side effects in patients given i/m tramadol with patients given epidural ropivacaine.

Side effect	Tramadol group		Epidural group	
	Patients			
	No.	%	No.	%
Nausea	3	6	0	0
Vomiting	2	4	0	0
Giddiness	0	0	2	4
Any other	0	0	0	0

Six% patients in tramadol group were found to have nausea and vomiting whereas epidural ropivacaine

showed no such side effect. Two patients in epidural group had giddiness whereas no such effect was seen with tramadol. The difference was statistically not significant (Table 11).

DISCUSSION

Ninety percent of patients in both groups were in 21 to 25 years age group. Mean age of patients in tramadol group was 23.14±4.06 and in epidural group was 22.92±4.21. The difference between age distribution and gestational ages of the two was statistically not significant which was similar to that seen in a randomized trial of epidural analgesia conducted by Sharma et al.[7] In the comparative study on epidural analgesia in labour (using lidocaine and fentanyl) versus no analgesia by Mousa et al, median of initial cervical dilation for all the patients was 4 cm which was similar to that seen in our study.[8] 86% patients in tramadol group and 80% patients in epidural group had an initial cervical dilation of 4 cm. All patients labelled the VAS score between 8 to10 before any analgesia was administered. After receiving 100 mg I/M tramadol, only 34% patients had a significant fall in VAS score (VAS≤5)while in the epidural ropivacaine group, 92% patients had a significant fall in VAS score. Douma et al conducted a randomised comparison of intravenous remifentanil patient-controlled analgesia with epidural ropivacaine/sufentanil during labour and reported the decrease in pain scores in the epidural group was significantly greater than the remifentanil group at all time intervals as is seen in our study.[9] Similar results were reported by Sharma et al. In our study patients in epidural group were significantly better satisfied compared to tramadol group. Loughnan et al conducted a randomized comparison of epidural (0.25% bupivacaine) versus I/M 100 mg pethidine for analgesia in labour where 83% patients in the epidural group had excellent pain relief during the first stage in contrast to only 56% patients in the parenteral pethidine group.[10] Time of onset of analgesia was defined as time interval between introduction of drug and any pain relief felt by the patient. Mean time of onset in tramadol group was 20.68±8.14 minutes while in epidural group was 12.82±3.76 minutes. This is comparable with that reported by Stienstra et al and Jyoti et al. Onset of analgesia with epidural ropivacaine was significantly faster compared to i/m tramadol.[11,12] In tramadol group, 4 patients underwent LSCS due to fetal distress. In epidural group, 5 patients underwent LSCS due to fetal distress and 1 patient had forceps delivery due to poor maternal bearing down efforts. The results of our study were similar to that by Mousa et al where no increase in rate of instrumental deliveries and cesarean section was seen in epidural group compared to the tramadol group. But the results of our study differ from that of Sharma et al which showed higher instrumental delivery rates with epidural compared to I/V meperidine because of use of bupivacaine instead of ropivacaine during epidural analgesia as bupivacaine has more effect on the motor nerves as compared to ropivacaine.

Patients undergoing vaginal delivery were compared for duration of the first and second stage of labour. The difference between the two groups was statistically not significant. The finding of our study is concordant to that found by Loughnan et al and Mousa et al.[8,10] However it differs from the conclusions of Sharma et al probably due to use of bupivacaine.[7] Six percent patients in tramadol group were found to have nausea and vomiting whereas epidural ropivacaine showed no such side effect. Our results differed from that of Mousa et al in that no hypotension was observed in the epidural group in the present study.[10] However two patients had transient giddiness. The results of tramadol group were similar to that conducted by Viegas et al, in that the side effects of tramadol were not significant.[13]

CONCLUSION

Maternal outcome in labour analgesia is similar with 100mg I/M tramadol and epidural ropivacaine. There is no significant difference between duration of labour, rate of LSCS, incidence of instrumental delivery in the two modes of analgesia. Analgesic efficacy and patient satisfaction with epidural ropivacaine seems to be better compared to intramuscular tramadol. There is paucity of research evidence about the relative effectiveness and side effects of tramadol compared with epidural analgesia using 0.2% ropivacaine. Well-designed trials of epidural analgesia using ropivacaine versus tramadol that addresses substantive labour outcomes are strongly recommended.

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REFERENCES

1. Eriksson C, Eriksson G, Westman K, Hamberg. Content of childbirth-related fear in Swedish women and men analysis of an open-ended question. J Midwifery Women Health. 2006;51:112-8.
2. Saisto T, Saisto R, Kaaja O, Ylikorkala E, Halesmäki. Reduced pain tolerance during and after pregnancy in women suffering from fear of labor pain. Anesthesiology. 2001;93:123-7.
3. Jouppila R, Hollmen A. The effect of segmental epidural analgesia on maternal and foetal acid-base balance, lactate, serum potassium and creatine phosphokinase during labour. Acta Anaesth Scand. 1976;20:259-68.
4. Lederman RP, Lederman E, Work B, McCann DS. Anxiety and epinephrine in multiparous labor: relationship to duration of labor and fetal heart rate pattern. Am J Obstet Gynecol. 1985;153:870-7.
5. Levinson G, Shnider SM, Lorimier AA, Steffenson JL. Effects of maternal hyperventilation on uterine blood flow and fetal oxygenation and acid-base status. Anesthesiology. 1974;40:340-7.

6. 6. Shnider SM, Abboud T, Artal R, Henriksen EH, Stefani SJ, Levinson G. Maternal catecholamines decrease during labor after lumbar epidural analgesia. Am J Obstet Gynecol. 1983;147:13-5.
7. Sharma SK, Alexander JM , Messick G. Cesarean delivery; a randomized trial of epidural analgesia versus intravenous analgesia during labour in nulliparous women. Anesthesiology. 2002;96:546-51.
8. Mousa WF, Al-Metwalli RR, Mostafa M. Epidural analgesia during labor 0.5% lidocaine with fentanyl versus 0.08% ropivacaine with fentanyl. Middle East J Anesthesiol. 2010;20(4):521-7.
9. Douma MR, Middeldorp JM, Verwey RA, Dahan A, Stienstra R. A randomised comparison of intravenous remifentanil patient controlled analgesia with epidural ropivacaine/sufentanil during labour. Int J Obstet Anesth. 2011;20(2):118-23.
10. Loughnan BA, Carli F, Romney M, Dore CJ, Gordon H. Randomized controlled comparison of epidural bupivacaine versus pethidine for analgesia in labour. Br J Anaesth. 2000;84:715-9.
11. Stienstra R, Jonker TA, Bourdrez P, Kuijpers JC. Ropivacaine 0.25% Versus Bupivacaine 0.25% for Continuous Epidural Analgesia in Labor: a double-blind comparison. Anesth Analg. 1995;80:285-9.
12. Jyoti M, Prabha S, Devika C. Programmed labour. J Obstet Gynecol India. 2006;56(1):53-5.
13. Viegas OAC, Benny K, Ratnam SS. Tramadol in labour pain in primiparous patients, a prospective comparative clinical trial. Eur J Obst Gynae Reproductive Bio. 1993;49(3):131-5.

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