International Journal of Reproduction, Contraception, Obstetrics and Gynecology
Taneja A et al. Int J Reprod Contracept Obstet Gynecol. 2017 Jul;6(7):2836-2840
www.ijrcog.org

pISSN 2320-1770 | eISSN 2320-1789

DOI: http://dx.doi.org/10.18203/2320-1770.ijrcog20172611

Original Research Article

Fetomaternal outcome in high-risk parturients receiving epidural analgesia using fentanyl with ropivacaine versus iv tramadol: a comparative study

Ashima Taneja[1]*, Kamaldeep Arora[2], Isha Chopra[1], Anju Grewal[3], Sushree Samiksha Naik[4], Geetika Sharma[1]

[1]Department of Obstetrics and Gynecology, Dayanand Medical College, Ludhiana, Punjab, India
[2]Department of Pediatrics, Dayanand Medical College, Ludhiana, Punjab, India
[3]Department of Anaesthesia, Dayanand Medical College, Ludhiana, Punjab, India
[4]Department of Obstetrics and Gynecology, AIIMS, Bhubaneswar, Odisha, India

Received: 24 May 2017
Accepted: 07 June 2017

***Correspondence:**
Dr. Ashima Taneja,
E-mail: kauraashima@gmail.com

ABSTRACT

Background: Labour analgesia has been recommended but sufficient data on use of labour epidural analgesia with ropivacaine and fentanyl combination during labour is not available.
Methods: A comparative study was conducted on 40 high risk labouring partuirents, randomly allocated to group A (iv tramadol) and group B (epidural analgesia with ropivacaine plus fentanyl). Assessments were done for fetal heart rate abnormality, mode of delivery, duration of labour, and Apgar score. The VAS score, patient satisfaction score, and complications were recorded.
Results: Group A had more number of instrumental deliveries compared to group B, the later had higher number of caesarean sections. No difference was observed in vaginal deliveries in both the groups. Pain relief was significant in patients of epidural group. The neonatal outcome was same in both the groups. Significant number of patients had a higher degree of satisfaction score in group B compared to group A.
Conclusions: Tramadol and epidural analgesia in labour are safe and effective. Patient satisfaction is significantly higher in epidural group as compared to the tramadol group.

Keywords: Epidural analgesia, Labour, Outcome, Tramadol, Vaginal delivery

INTRODUCTION

Pain during labour is one of the worst experiences in the life of a woman, and its relief is an important issue.[1] Most women request for some forms of analgesia (pharmacological/non-pharmacological) to get rid of this excruciating pain. Few women also opt for caesarean section to avoid the bad experience of painful labour and/or episiotomy. Painful labour also reduces utero-placental blood flow.[1] To counter all these, effective analgesia is needed to eliminate/attenuate pain in labour.[2] Various pain-relieving methods are available since long time that include: systemic administration of medications, inhalational medications, transcutaneous nerve stimulation (TENS), neuro-axial blockade, and epidural analgesia. Of them, epidural analgesia is the most accepted method as it has been found to be both safe (both for the mother and the neonate), and effective.[3-6] However, there is some doubt regarding its effect on the duration of labour (some think that it may increase the

rate of instrument application or operative delivery including caesarean section).[7,8]

Ropivacaine is a local anaesthetic agent which produces less motor blockade and thus produces a higher patient satisfaction when used as an epidural anaesthetic agent with or without other agents.[2,6] Tramadol is a potent opioid analgesic that blocks both nor-adrenergic and serotonergic receptor produces less/no maternal sedation and respiratory depression in the neonate.[2,6] It can be used via oral, intramuscular, intravenous and epidural routes with minimal side effects. Hence this study was designed to investigate the safety and efficacy of epidural analgesia using ropivacaine with fentanyl compared to intravenous tramadol in high risk labouring parturients. The comparison is made with intravenous tramadol as use of tramadol for labour analgesia has been recommended.[2,6,9,10]

METHODS

A comparative study was conducted on forty high-risk women admitted in labour room for delivery in a tertiary care hospital in North India. They were informed about pain relief during labour using analgesia, their willingness and written consent was taken. Parturient were allocated to two groups by method of randomization. Group A (tramadol: 1 mg/kg/body-weight intravenous bolus followed by 100 mg in 500 ml ringer lactate drip iv); and group B (epidural analgesia using 0.2% ropivacaine and 2ug/ml fentanyl). High risk parturient that include heart disease in pregnancy, hypertensive disease of pregnancy, fetal growth restriction, gestational diabetes mellitus, previous caesarean section, any medical disease complicating pregnancy (e.g. anaemia, jaundice, SLE etc.), gestational age 34-41 weeks, primipara/multipara, during active stage of labour ≥3 cm, vertex presentation, spontaneous or induced labour were included. Those with refusal, abnormal presentation, active maternal hemorrhage, infection at epidural needle site, maternal coagulopathy, and cephalo-pelvic disproportion were excluded from the study.

Hemogram and coagulation profile was done. Experienced anaesthesiologist gave an epidural test dose of 3 ml of lignocaine, 2% with epinephrine 1:200,000 to patients in group B. Five minutes later, after confirming a negative response to this test dose, analgesia was initiated using 2 ml increments of ropivacaine 0.2% and 2µg/ml fentanyl repeated at 10 min and 20 min. A continuous epidural infusion using the patient controlled epidural analgesia (PCEA) infusion device with the same drug was started at a rate of 6-10ml/h to maintain an adequate analgesia. The PCEA infusion device was programmed with the standardized parameters of a 2ml bolus and a 10min lockout period using the study solution. Additional epidural analgesic study solution (2ml) was delivered by the patient by pressing the demand PCEA device, when desired or when visual analogue scale (VAS) more than 5. Assessments were made in both groups every 10 min for the first 30 min, and finally every 30 min till delivery. Parturient appraisal included assessment of non-invasive blood pressure (NIBP), pulse rate, fetal heart rate, oxygen saturation, and pain relief completion of a 10cm linear visual analogue scale for pain (VAS) at the peak of contractions (0=no pain; 10=worst pain imaginable).11 Any fetal heart rate abnormalities was assessed and managed accordingly. Duration of each stage of labour, total duration of labour, mode of delivery (spontaneous /forceps/ventouse/lower segment caesarean section), indication of assisted delivery, duration and rates of epidural infusion and iv tramadol, number and dose of supplementary top ups and patient satisfaction score was recorded. The neonatal outcome was studied with regard to Apgar score at 1 min and 5 min, neonatal birth weight. Adverse effects such as hypotension, nausea/vomiting, leg weakness, shivering, drowsiness, backache was recorded. Analgesia by either technique was started after establishment of active stage of labour i.e. cervix is >3 cm dilated. Study protocol was approved by ethical committee of the institution. Patient consent was prior to enrolment in the study.

Statistical analysis

The database was mounted in the Excel program, and the statistical analysis was performed with SPSS software (version 16.0, SPSS Inc., USA). The mean between the two groups were compared using the student's t-test. Proportions were compared using Chi-square test or Fischer's exact test. The level of significance considered was <0.05.

RESULTS

The mean (range) age at presentation was 28 (27-32) years, and the distribution is shown in Table 1.

Table 1: Comparison of maternal age and gestational age of neonates

	Group A (n=20)	Group B (n=20)
Maternal age (years)		
25-30	14 (70%)	16 (80%)
31-35	6 (30%)	4 (20%)
Gestational age (weeks)		
36-37	1 (5%)	1 (5%)
37-38	8 (40%)	9 (45%)
38-39	7 (35%)	8 (40%)
39-40	4 (20%)	2 (10%)

The maternal age group of 25 to 30 years was 70% in group A and 80% in group B; and of 31 to 35 years was 30% in group A and 20% in group B. There was no significant difference between the two groups (p=0.32). The cervical dilatation at first dose of the intervention (i.e. initial cervical dilatation) was comparable between the two groups. The dilatation was >4cm in 15 (75%) cases in group A and 16 (80%) cases in group B, >5cm in

3 (15%) cases in group A and 2 (10%) cases in group B, and >6 cm in 2 (10%) cases each in group A and B. There was no significant difference between the two groups (p=0.54).

Analgesic efficacy: Visual analogue scale (VAS) score

Mean VAS score was compared between the two groups as shown in Table 2. Before starting of the interventions/drugs, the VAS score varied from 7-10 in the two groups (p=0.46). After the intervention started, the VAS score decreased faster in group B compared to group A. Finally, the mean score in group A was 6.4, and in group B was 3.15. This means, the parturient in group B faced a significantly better analgesic efficacy compared to those in group B (p=0.01).

Table 2: Comparison of VAS (visual analogue scale) score between the two groups.

	Group A (n=20)	Group B (n=20)
0-1	2 (10%)	9 (45%)
2-3	2 (10%)	4 (20%)
4-5	5 (25%)	5 (25%)
6-7	5 (25%)	1 (5%)
8-10	6 (30%)	1 (5%)

VAS score at the peak of contractions: 0=no pain; 10=worst pain imaginable, Group A vs Group B, p = 0.01

Patient satisfaction score

Patient satisfaction score was compared between the two groups, and provided in Table 3.

Table 3: Patient satisfaction score in the two groups.

Patient satisfaction	Group A (n=20)	Group B (n=20)
Average	65%	35%
Excellent	0	10%
Good	10%	55%
Poor	25%	0

Group A vs Group B, p=0.02

The score was average in 65% in group A compared to 35% in group B, excellent in none in group A compared to 10% in group B, Good in 10% in group A compared to 55% in group B, Poor in 25% in group A compared to none in group B. The overall score was significantly higher in the group B compared to the group A (p=0.02).

Comparison of stages of labour

Comparison of stages of labour was done between the two groups. The durations of first (520.83min vs. 488.33min), second (43.8min versus 45.56min) and third stages of labour (16.39 versus 14.72min) in both the groups were comparable. The total duration of labour in group A was 489.00min and in group B was 493.75min. There was no significant difference between the two groups.

Mode of delivery

The modes of deliveries have been provided in Table 4. Group A had higher number of instrumental deliveries compared to group B (35% versus 30%), while Group B had more number of caesarean sections (10% versus 15%). But these differences were not statistically significant. The number of vaginal deliveries was equal in both the groups.

Table 4: Mode of delivery in both the groups

Mode of delivery	Group A (n=20)	Group B (n=20)
Instrumental	7 (35 %)	6 (30%)
Vaginal	11 (55%)	11 (55%)
LSCS	2 (10%)	3 (15%)

Neonatal details

The gestational age of neonates was compared between the two groups as shown in Table 1. The gestational age of neonates of 36 to 37 weeks was 5% in each group; 37 to 38 weeks was 40% in group A and 45% in group B; and of 38 to 39 weeks was 35% in group A and 40% in group B; and of 39 to 40 weeks was 20% in group A and 10% in group B.

Table 5: Apgar score at 1 min and 5 min in both the groups.

	Group A (n=20)	Group B (n=20)
	Mean	Mean
Apgar score at 1 min	7.85	8.80
Apgar score at 5 min	8.00	9.00

The mean Apgar score at 1 minute and 5 minutes among the two groups were comparable, which has been provided in Table 5. The mean 1 min Apgar score was 7.85 in group A, and 8.8 in group B, whereas the 5 min Apgar score was 8.0 in group A, and 9.0 in group B. Three neonates in each group developed physiological jaundice not requiring any therapy.

Maternal complications/adverse events

The following complications/adverse events were noted as shown in Table 6. Nausea developed in 25% cases in group A and 5% cases in group B. Giddiness in 5% cases in group A only. Vomiting in 20% cases in group A only. Transient hypotension, leg weakness, and backache developed in 5% of each case in group B. Atonic post-partum haemorrhage (PPH) developed in 5% cases in group A, and 10% cases in group B. All these were controlled by uterine massage, oxytocin infusion, and injection methergin. Retained placenta developed in 10%

cases only in group B. Manual removal of placenta (MRP) was done in these cases.

Table 6: Comparison of maternal complications between the two groups.

	Group A (n=20)	Group B (n=20)
Nausea	5 (25%)	1 (5%)
Giddiness	1 (5%)	0
Vomiting	4 (20%)	0
Hypotension (transient)	0	1 (5%)
Leg weakness	0	1 (5%)
Backache	0	1 (5%)
Atonic PPH	1 (5%)	2 (10%)
Retained placenta	0	2 (10%)

DISCUSSION

In the present study, we found the following results. The mean (range) age at presentation was 28 (27 – 32) years. The gestational age of neonates and Apgar score was compared between the two groups. Similar was the finding by previous authors.[6,9,10] The cervical dilatation at first dose of the intervention (i.e. initial cervical dilatation) was comparable between the two groups, and also corroborates with findings of previous study.[6,12]

In the present study, the mean VAS score was significantly lower in the epidural group (significant pain relief/analgesia) compared to the tramadol group. Similar results were obtained by others as well.[6,13] The overall patient satisfaction score was significantly higher in the epidural group compared to the tramadol group, which also corroborates with a previous study.[6]

The total duration of labour in the tramadol group was 489.00 min and in epidural group was 493.75 min. There was a slight but not significant prolongation in the epidural group. This supports the previous study findings that epidural analgesia does not significantly increase the labour duration.[6-8] Tramadol group had higher number of instrumental deliveries. This can be explained by the sedative effect of tramadol affecting the maternal bearing down efforts in second stage. Similar findings have been reported by other studies.[14-16] But, the caesarean section rate was higher in the epidural group compared to the tramadol group. This was mostly due to non-progression of the labour. This was not statistically significant, but may be clinical significant. This was in accordance with a previous study,[6] but not supportive of other studies.[10,12] Successful vaginal deliveries were similar in both the groups.

Regarding the complications/adverse observed in the present study, all except the transient hypotension was in accordance with one study.[6] Tramadol being an opioid is known to cause nausea and vomiting. The transient hypotension noted in one patient corroborates with the findings of a previous study.[12]

Neonatal outcome was not affected by any type of analgesia. Apgar score in both the groups was comparable as effective epidural analgesia reduces stress related effects on the mother and fetus and decreasing fetal distress. Further, more stable hemodynamics and absence of severe hypotension led to preserved utero-placental blood flow which thereby did not jeopardize the fetal marginal reserves. Similar results were observed by other workers.[6,13,17]

CONCLUSION

To conclude, tramadol and epidural analgesia in labour is safe and effective, though epidural analgesia was better than iv tramadol. Patient opting for epidural analgesia should be counselled regarding increased risk of caesarean delivery. No difference in the neonatal outcome was noted between the two groups.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

REFERENCES

1. Long J, Yue Y. Patient controlled intravenous analgesia with tramadol for labour pain relief. Chin Med J. 2003;116:1752-5.
2. Hawkins JL. Epidural analgesia for labour and delivery. N Engl J Med. 2010;362:1503-10.
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. 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.
6. Lamba A, Sardana P, Kaur R. Comparison of parenteral tramadol and epidural ropivacaine for labour analgesia: a prospective clinical study Int J Reprod Contracept Obstet Gynecol. 2016;5:1722-1727.
7. Anim-Somuah M, Smyth RM, Jones L. Epidural versus non-epidural or no analgesia in labour. Cochrane Database Syst Rev. 2011:CD000331.
8. Bakhamees H, Hegazy E. Does epidural increase the incidence of caesarean delivery or instrumental labor in Saudi populations? Middle East J Anaesthesiol. 2007;19:693-704.
9. Chandnani K, Sainee, HB. Pain relief in labour: tramadol verses pentazocine. Int J Reprod Contracept Obstet Gynecol. 2013;2:186-9.

10. Sharma SK, Alexander JM, Messick G. Cesarean delivery; a randomized trial of epidural analgesia versus intravenous analgesia during labour in nulliparous women. Anesthesiol. 2002;96:546-51.
11. McCormack HM, Horne DJ, Sheather S. Clinical applications of visual analogue scales: a critical review. Psychol Med. 1988;18:1007-19.
12. 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;20:521-7.
13. Jaitley A, Singh S, Srivastava V, Nagrath A, Prajapati N C, Singh R. A Comparison between epidural and IV tramadol for painless labor and effect on perinatal outcome. J Obstet Gynecol India. 2011;61:42-7.
14. Desai P, Patel P, Gupta A, Virk G K, Sinha A. Epidural analgesia in labor. J Obstet Gynecol India. 2006;56:417-22.
15. Impey L, Macquillan K, RCM, Lobsonm M. Eg'inral analgesia need not increase operative delivery rates. Am J Obstet Gynecol. 2000;182:358-63.
16. Fyneface S, Mato CN, Anya SE. Epidural anesthesia: views and outcomes of women in labor in a Nigerian hospital. Ann Afr Med. 2009;8:250-6.
17. Halvadia SH, Halvadia HB, Joshi RM, Upadhyaya DP. A study of feto maternal outcome of epidural analgesia during labor. Natl J Med Res. 2013;3:184-86.

Cite this article as: Taneja A, Arora K, Chopra I, Grewal A, Naik SS, Sharma G. Fetomaternal outcome in high-risk parturients receiving epidural analgesia using fentanyl with ropivacaine versus iv tramadol: a comparative study. Int J Reprod Contracept Obstet Gynecol 2017;6:2836-40.