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Original Research Article

A Pilot Study - Efficacy of 0.15% Ropivacaine with Fentanyl for Management of Epidural Labor Analgesia in Primigravida Parturient

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Conflict of interest: Nil

Abstract:

Background: Ropivacaine is considered to have better safety profile and differential block compared to Bupivacaine. Ropivacaine in Labor Epidural Analgesia can be useful in providing good pain relief with better maternal satisfaction due to less motor blockade**.**

Materials & Method: This pilot study was conducted in 30 consenting nulliparous primigravida and Epidural labor analgesia was given by 0.15 % Ropivacaine with fentanyl. Our primary objective is to assess the analgesic efficacy using VAS score and degree of motor blockade of Epidural 0.15% Ropivacaine with fentanyl in nulliparous parturient undergoing labour epidural analgesia. Our secondary objective was the obstetric outcome in terms of rate of normal, instrumental vaginal or caesarean delivery, any side effects like nausea, vomiting, hypotension, maternal satisfaction score and the neonatal outcome.

Observations and Results: Effective Ambulatory Labor Analgesia was observed in all 30 parturient with no failure rate. VAS score was highly statically significant ($p < 0.001$) between pre- bolus and post- infusion. None of the parturient required rescue analgesia or complained of VAS > 3 throughout the study. We found no significant motor blockade in our study. All Parturient were pain free, ambulatory with no motor blockade. Maternal Satisfaction score was excellent in 86.66% of parturient with no parturient complained of poor pain relief.

Conclusion: In our pilot study we conclude that 0.15% Ropivacaine provide excellent walking epidural labor analgesia with no motor blockade resulting in good maternal satisfaction and neonate outcome.

Keywords: Ropivacaine, Epidural Labor analgesia, Motor blockade, Maternal Satisfaction.

Introduction

Labor analgesia is an age-old method practiced all over the world. With the introduction of the epidural technique, which is considered safe for both mother and child, more and more women are opting for pain relief during delivery. There are various considerations regarding techniques like using intermittent doses, continuous infusion epidural analgesia (CIEA), patient-controlled epidural analgesia, Local anaesthesia drugs, and their concentration.

Ropivacaine, a long-acting amide local anesthetic agent, when compared to Bupivacaine seems to produce less systemic toxicity, comparable sensory block, but less intense motor blockade of shorter duration. [1,2] However, some studies done with 0.2% Ropivacaine have showed some degree of motor blockade in Epidural labor analgesia. [3,4] One of the major drawbacks of Epidural labor analgesia are chances of motor blockade, which can adversely affect mode of delivery and decreases maternal satisfaction. We did this pilot study to study efficacy of 0.15% ropivacaine in terms of effective labour analgesia, motor blockade and maternal satisfaction. We hypothesized that 0.15% ropivacaine will produce effective analgesia with lesser degree of blockade.

Our primary objective is to assess the analgesic efficacy and degree of motor blockade of Epidural 0.15% Ropivacaine with fentanyl in nulliparous parturient undergoing labour epidural analgesia. Our secondary objective was the obstetric outcome in terms of rate of normal, instrumental vaginal or caesarean delivery, any side effects, maternal satisfaction score and the neonatal outcome.

Materials and Methods:

This pilot study was conducted on 30 nulliparous parturient after taking approval of Institutional Ethical Committee in a tertiary hospital over a period of 3 year. A written informed consent was taken from all parturient demanding Epidural labor analgesia admitted in the obstetric labor room and

were selected for our pilot study by using simple random sampling.

Inclusion criteria included nulliparous women aged 18 yrs-35yrs with full term (37-42 weeks) cephalic singleton pregnancies, belonging to ASA -1 & 2, with cervix dilatation more than 3 cm and in active labor who are willing for labour epidural analgesia.

Exclusion criteria were multiparous, parturient having bleeding dyscrasia, thrombocytopenia, obesity, fetal distress, fetal anomalies, antepartum haemorrhage, local infection over spine, spinal deformities, non- vertex presentation, allergy to study drugs and parturient refusal. Detailed Preanesthetic check up with physical and clinical examinations was done in all consenting parturient. Before the placement of epidural catheter, parturient was explained about VAS score and was asked to qualify the pain at the peak of uterine contraction on the VAS score of 0-10 with 0 = no pain and 10 = unbearable pain.

After confirming NBM status and checking informed written consent, an intravenous access with 18 G intra-catheter was taken in Labor room. Preloading was done with 500 ml of Ringer's lactate solution. After attaching standard ASA monitors vital parameters was noted before giving epidural block. Resuscitation cart and emergency drugs were kept ready for managing any complications like hypotension, bradycardia etc. Under all aseptic precaution, epidural catheter was placed with the parturient in sitting position, using 18-gauge Tuohy needle. Epidural space was identified by loss of resistance technique to air via midline approach at L3-L4 interspace. Epidural catheter was inserted and fixed at 3 cm in epidural space. Epidural placement of catheter was confirmed by negative aspiration for blood and cerebrospinal fluid. Catheter was secured and parturient allowed to be in the supine position with left uterine displacement. Drugs was prepared under strict aseptic precaution and labelled by senior anaesthesiologist. Ropivacaine 0.15% was prepared by taking 6 ml of 0.2% of ropivacaine and diluting it with 2ml of 0.9% normal saline.

Parturient were given epidurally 8ml of 0.15% Ropivacaine with 25mcg Fentanyl bolus followed by infusion of 0.15% Ropivacaine at the rate of 10ml/hr. 3ml of Epidural study drug was given test dose after negative aspiration of blood and C.S.F. If no clinical signs of intravascular or intradural placement of catheter are seen, additional 5ml of study drug was given 5mins after test dose.

The study drug was injected as incremental boluses after negative aspiration of blood and CSF. Onset of analgesia was defined as time taken to VAS become <3 from first bolus dose. If analgesia was not adequate (VAS>3) after 20 mins of bolus dose.8ml of study drug was to be given again as 2nd initial dose. If still pain relief was inadequate, parturient was withdrawn from study. The end point of the study was baby delivery or when parturient required caesarean section due to fetal or maternal indication. In Labor room, Epidural infusion of Ropivacaine 0.15% was started at 10ml/hr and parturient was monitored till the delivery of baby. If parturient complained of pain VAS>3, she would be given rescue analgesia of 4ml of 0.15% Ropivacaine as bolus dose.

All hemodynamic parameter like Heart rate, Non-invasive blood pressure, Oxygen saturation (Spo2) was monitored. Fetal heart rate monitoring was done by cardiotocograph. Onset and extent of motor blockade was recorded after epidural bolus dose using Bromage motor score (BMS) at 30 mins and then hourly. Grade 1 = free movements of legs and feet, [nil = 0%], Grade 2 = just able to flex knee with free movements of feet [partial = 33%], Grade 3 = unable to flex knee, but with free movements of feet [almost complete 66%], Grade 4 = unable to move legs or feet [complete 100%].Extent of sensory block measured by pin prick method for every 2, 5,10 minutes up to half an hour and then every half hourly till delivery of baby and expulsion of the placenta. Analgesia was assessed by using VAS (Visual Analog Score) by asking parturient to grade pain at the peak of uterine contractions every hourly. Duration of 1st,2nd and 3rd stage, mode of delivery, APGAR score of baby at 5 mins and 10 mins was noted. Parturient was encouraged to walk, sit, and change positions in bed.

Any adverse effects like headache, backache, hypotension, shivering, nausea, vomiting, pruritis, respiratory depression and urinary retention were noted and if present was treated accordingly for 24 hrs. Hypotension was defined as fall in mean arterial pressure >20% of base line value and was treated with bolus of 6mg ephedrine intravenously. Bradycardia was defined as heart rate< 60 bpm and was treated with 0.6mg atropine sulphate intravenously. Maternal Satisfaction score on a four- point scale (3= excellent, 2 = good, 1= fair, 0 = poor) was noted for epidural pain relief.

Statistical analysis was done by observational descriptive statistics, analysis of variance with student's t test. $P < 0.05$ was considered significant. Other values are described as mean ± standard deviation and percentage.

Results

Effective Ambulatory Labor Analgesia was observed in all 30 parturient with no failure rate. Demographic profile including age, weight, and height of 30 parturient along with onset of sensory block is depicted in Table-1.

Mean Onset of Analgesia was 7.06 ± 2.52 mins. After epidural bolus dose of 1.5% Ropivacaine 36.6% of parturient achieved VAS <3 within 0-5mins, while 63.3% of parturient had pain relief within 6-15 mins.

Table 1: Demographic profile and Onset of Sensory block.

Parameter	Mean ± SD
Age (Years)	23.56 ±2.44
Weight (Kg)	57.96 ±3.54
Height (Cm)	153.83 ±1.48
Onset Of Sensory Block (Min)	7.06±2.54

Upper segmental level of sensory block reached was T8 in 40% of parturient. Extent of the sensory block based on dermatomes shown in Table 2.

Table 2: Extent of the sensory block

Extent Of Sensory Block	Number Of Patients	Percentage
T6	6	20%
T7	10	33.33%
T8	12	40%
T10	2	6.66%

In our study 22 parturient had normal vaginal delivery, 5 assisted vaginal delivery and 3 patients required LSCS due to non-reassuring non-stress test. Distribution of patients with respect to mode of delivery shown in Table 3.

Table 3: Mode of Delivery

Mode Of Delivery	Number Of Patients	Percentage
Normal Vaginal	22	73.33%
Assisted Vaginal	5	16.66%
LSCS	3	10%

Total duration of Labor in terms of 1st stage, 2nd stage and 3rd stage of Labor is shown in Table 4.

Table 4: Duration of Labor

Duration Of Labor (In Mins)	Mean ± SD
From 3cm Cervical Dilatation To Full Dilatation	219.9 ± 65.69
Full Dilatation To Delivery Of Baby	23.9 ± 5.17
Delivery Of Baby To Expulsion Of Placenta	9.9 ± 1.32

VAS score was highly statically significant ($p < 0.001$) between pre- bolus and post- infusion (Table -5). None of the parturient required rescue analgesia or complained of VAS > 3 throughout the study. We found no significant motor blockade in our study. All Parturient were pain free, ambulatory with no motor blockade (BMS - Grade 0) and so actively participated in labor process.

Table 5: VAS score Pre-bolus and Post-Infusion.

	Mean ± SD		
VAS at	**prebolous**	**postinfusion**	**p value**
10 mins	7.9 ± 0.71	1.77±0.63	<0.001
20 mins	7.9 ± 0.71	1.37 ± 0.67	<0.001
30 mins	7.9 ± 0.71	0.93 ± 0.64	<0.001
1st h	7.9 ± 0.71	0.87 ± 0.68	<0.001
1.5 h	7.86 ± 0.69	0.62 ± 0.73	<0.001
2nd h	7.86 ± 0.69	0.66 ± 0.72	<0.001
2.5 h	7.89 ± 0.71	0.65 ± 0.74	<0.001
3rd h	7.89 ± 0.71	0.65 ± 0.74	<0.001
3.5 h	7.86 ± 0.73	0.71 ± 0.78	<0.001
4th h	7.72 ± 0.82	0.78 ± 0.81	<0.001
4.5 h	7.7 ± 0.82	0.9 ± 0.74	<0.001
5th h	7.71 ± 0.95	1.14 ± 0.69	<0.001
5.5 h	7.75 ± 0.5	1 ± 0	<0.001
6th h	7.5 ± 0.71	1 ± 0	<0.001
6.5 h	7.5 ± 0.71	1 ± 0	<0.001

We found that the haemodynamic parameters of parturient were stable throughout the study with no episode of hypotension or bradycardia seen, none of the parturient required either ephedrine or atropine. One parturient complained of Pruritus (3%) and 2 cases of nausea (6%) were observed in the parturient which was treated accordingly. No case of respiratory depression, vomiting, shivering, and urinary retention was seen. No Dural puncture or PDPH was observed among parturient. Side Effects are shown in Table-6.

Table 6:

Side Effects	No. of Parturient	Percentage (%)
Pruritis	1	3
Nausea	2	6
Vomiting	0	0
Hypotension	0	0
Bradycardia	0	0

Maternal Satisfaction score was excellent in 86.66% of parturient with no parturient complained of poor pain relief. (Table-7) This can be attributed to excellent pain relief with no motor blockade provided by epidural ropivacaine with fentanyl, good rapport along with preprocedural counselling, and good neonatal outcome.

Table 7:

Maternal Satisfaction Score	Number Of Patients	Percentage
Excellent	26	86.66%
Good	2	6.66 %
Fair	2	6.66 %
Poor	0	0

Neonatal outcome was good with Apgar scores >7 at 1 min and 5 mins with no NICU admission (Table-8). Maximum Apgar score at 1 min and 5 min was 9 and 10, respectively. The good fetal outcome can be attributed to hemodynamic stability due to the usage of low local anaesthetic concentration.

Table 8:

Apgar score	MEAN ± SD
Apgar score at 5 mins	7.40±0.56
Apgar score at 10 mins	9.33±0.66

Discussion

ROPIVACAINE is an aminoamide group of local anaesthetic which is commercially available as pure S enantiomer. There is greater degree of differential block with ropivacaine at low concentration and the property of producing frequency dependent block results in considerable clinical advantages in providing analgesia with minimal motor block. [5] In preclinical studies, ropivacaine was shown to have less central nervous and cardiovascular system toxicity than bupivacaine. [6,7]

Ropivacaine has a better safety profile and provides more differential block when given epidurally, allowing for a better separation between sensory and motor block. These features can be used to its advantage in obstetrics and in postoperative epidural pain relief. [8] Several studies compared different concentrations of ropivacaine and bupivacaine for efficacy, potency, toxicity, and obstetric outcome in epidural labor analgesia and found Ropivacaine better in terms of significantly less motor blockade. [9,10,11] In a meta-analysis done by Writer WD.et.al comprising approximately 400 parturient designed to compare ropivacaine and racemic bupivacaine for labour analgesia with respect to mode of delivery and neonatal outcome, it was shown that the use of ropivacaine was associated with significantly less motor block, more spontaneous vaginal deliveries, and less instrumental deliveries. [12] However, 0.2% Ropivacaine in Epidural labor analgesia has been associated with motor blockade during continuous epidural infusion. [13] The main concern regarding epidural labour analgesia is motor blockade which may increase the rate of instrumental vaginal delivery. [14] Since Ropivacaine produces lesser degree of motor blockade, so we wanted to investigate the effect of decreasing the concentration to 0.15% Ropivacaine on labor analgesia, motor blockade, progress of labor, obstetric outcome, and maternal satisfaction. G. Capogna.et al studied Minimum local anaesthetic concentration (MLAC) of epidural bupivacaine and ropivacaine for women in the first stage of labour which was determined by the up-down sequential allocation technique. They found that MLAC of ropivacaine was 0.156 and the MLAC of bupivacaine was 0.093. The analgesic potency of ropivacaine was 0.60 (0.47–0.75) relative to bupivacaine. They found that ropivacaine requires a 68% upward adjustment of dose to achieve equivalent analgesic potency with bupivacaine. [15] Polley LS.et.al in their study also concluded that Ropivacaine was significantly less potent than Bupivacaine, with a potency ratio of 0.6 (95% confidence interval, 0.49-0.74) for epidural analgesia in the first stage of labor. [16] So while decreasing the concentration, potency of Ropivacaine should be considered in view of providing effective labor analgesia.

We found that 0.15% Ropivacaine in this concentration provided effective labor analgesia without any significant motor blockade. An opioid can be combined with local anaesthetic to reduce the incidence of side-effects and to improve the quality of analgesia for the relief of labour pain. [17] In our study we added fentanyl to achieve better analgesia and to reduce the requirement of local anesthetic drug. This can be attributed to less

requirement of Ropivacaine with no breakthrough pain and no motor blockade seen in our study.

In our study there were no significant side effects like bradycardia, or hypotension observed, only 1 parturient complained of pruritis and 2 patients had nausea. Our observations are similar to a study done by Campbell. et.al found that a combination of ropivacaine (0.08%) and fentanyl (2 µg/mL) when compared to Bupivacaine, provided effective labor analgesia without causing clinically significant adverse maternal or fetal effects. [18] Chhetty YK. et. al. compared 0.125% and 0.2% ropivacaine both mixed with fentanyl 2mcg/ml used for epidural labor analgesia in 80 parturient.

They found both concentrations are effective in producing epidural labor analgesia, but 0.2% concentration was found to be superior in terms of faster onset, prolonged duration, and lesser breakthrough pain. [19] While decreasing the concentration of Ropivacaine, we should consider the quality of epidural analgesia as breakthrough pains may decrease maternal satisfaction.

We found in our study that 0.15% ropivacaine with fentanyl provides satisfactory ambulatory epidural analgesia with good maternal satisfaction without any significant side effects. The limitation of our study is a small sample size.

Conclusion

In our pilot study we found that 0.15% Ropivacaine with fentanyl provides excellent ambulatory epidural labor analgesia with no motor blockade and significant side effects resulting in good maternal satisfaction and fetal outcome.

References

1. Brockway MS, Bannister J, McClure JH, McKeown D, Wildsmith JA. Comparison of extradural ropivacaine and bupivacaine. Br J Anaesth. 1991 Jan; 66(1):31-7.
2. Morrison LM, Emanuelsson BM, McClure JH, Pollok AJ, McKeown DW, Brockway M, Jozwiak H, Wildsmith JA. Efficacy and kinetics of extradural ropivacaine: comparison with bupivacaine. Br J Anaesth. 1994 Feb; 72(2):164-9.
3. Sia AT, Chong JL. Epidural 0.2% Ropivacaine for Labour Analgesia: Parturient-Controlled or Continuous Infusion? Anaesthesia and Intensive Care. 1999; 27(2):154-158.
4. M. Dresner, J. Freeman, C.Calow, A. Quinn, J. Bamber, Ropivacaine 0.2% versus bupivacaine 0.1% with fentanyl: a double blind comparison for analgesia during labour, BJA: British Journal of Anaesthesia, Volume 85, Issue 6, 1 December 2000, Pages 826–829.
5. McClure JH. Ropivacaine. Br J Anaesth. 1996 Feb; 76(2):300-7.
6. Reiz S, Häggmark S, Johansson G, Nath S. Cardiotoxicity of ropivacaine--a new amide local anaesthetic agent. Acta Anaesthesiol Scand. 1989 Feb; 33(2):93-8.
7. Feldman HS, Arthur GR, Covino BG. Comparative systemic toxicity of convulsant and supraconvulsant doses of intravenous ropivacaine, bupivacaine, and lidocaine in the conscious dog. Anesth Analg. 1989 Dec; 69(6): 794-801.
8. Stienstra R. The place of ropivacaine in anesthesia. Acta Anaesthesiol Belg. 2003; 54(2): 141-8.
9. Eddleston JM, Holland JJ, Griffin RP, Corbett A, Horsman EL, Reynolds F. A double-blind comparison of 0.25% ropivacaine and 0.25% bupivacaine for extradural analgesia in labour. Br J Anaesth. 1996 Jan; 76(1):66-71.
10. Aşlk, I., Göktuğ, A., Gülay, I., Alkiş, N., & Uysalel, A. (2002). Comparison of bupivacaine 0.2% and ropivacaine 0.2% combined with fentanyl for epidural analgesia during labour. European Journal of Anaesthesiology, 19(4), 263-270.
11. Meister, Greg C. MD; D'Angelo, Robert MD; Owen, Medge MD; Nelson, Kenneth E. MD; Gaver, Renee MD. A Comparison of Epidural Analgesia with 0.125% Ropivacaine with Fentanyl Versus 0.125% Bupivacaine with Fentanyl during Labor. Anesthesia & Analgesia 90(3): 632-637, March 2000.
12. Writer WD, Stienstra R, Eddleston JM, Gatt SP, Griffin R, Gutsche BB, Joyce TH, Hedlund C, Heeroma K, Selander D. Neonatal outcome and mode of delivery after epidural analgesia for labour with ropivacaine and bupivacaine: a prospective meta-analysis. Br J Anaesth. 1998 Nov; 81(5):713-7.
13. M. Dresner, J. Freeman, C.Calow, A. Quinn, J. Bamber, Ropivacaine 0.2% versus bupivacaine 0.1% with fentanyl: a double-blind comparison for analgesia during labour, BJA: British Journal of Anaesthesia, Volume 85, Issue 6, 1 December 2000, Pages 826–829.
14. Aşlk, I., Göktuğ, A., Gülay, I., Alkiş, N., & Uysalel, A. Comparison of bupivacaine 0.2% and ropivacaine 0.2% combined with fentanyl for epidural analgesia during labour. European Journal of Anaesthesiology, 2002;19(4): 263-270.
15. Capogna G, Celleno D, Fusco P, Lyons G, Columb M. Relative potencies of bupivacaine and ropivacaine for analgesia in labour. Br J Anaesth. 1999 Mar;82(3):371-3.
16. Polley LS, Columb MO, Naughton NN, Wagner DS, van de Ven CJ. Relative analgesic potencies of ropivacaine and bupivacaine for epidural analgesia in labor: implications for therapeutic indexes. Anesthesiology. 1999 Apr; 90(4):944-50.

17. Ruban P, Sia AT, Chong JL. The effect of adding fentanyl to ropivacaine 0.125% on patient-controlled epidural analgesia during labour. Anaesth Intensive Care. 2000 Oct; 28(5):517-21.
18. Campbell, David C. MD, MSc, FRCPC; Zwack, Rhonda M. MD; Crone, Lesley-Ann L. MD, FRCPC; Yip, Ray W. MD, FRCPC. Ambulatory Labor Epidural Analgesia: Bupivacaine versus Ropivacaine. Anesthesia & Analgesia 90(6): p 1384-1389, June 2000.
19. Chhetty YK, Naithani U, Gupta S, Bedi V. Epidural labor analgesia: A comparison of ropivacaine 0.125% versus 0.2% with fentanyl. J Obstet Anaesth Crit Care 2013;3:16-22.