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Comparision of ropivacaine 0.2% with or without clonidine in epidural labor analgesia: A randomised controlled study

B Kanchanamala[1], V J Karthik[2,*], N Keerthana[3], C Kokila[4]

[1]*Government Medical College, Omandurar Government Estate, Chennai, Tamil Nadu, India*
[2]*Kilpauk Medical College, Chennai, Tamil Nadu, India*
[3]*Stanley Medical College, Chennai, Tamil Nadu, India*
[4]*Chengalpattu Medical College, Tamil Nadu, India*

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ABSTRACT

Introduction: Epidural labour analgesia is considered as the gold standard of pain relief for paturients inspite of the hesitancy that is prevalent in our country in providing pain-free labour. There are several other pharmacological and non pharmacological methods available for providing labour analgesia. Local anaesthetic is an indispensable drug for administering epidural labour analgesia Ropivacaine is the most widely used local anaesthetic for labour analgesia because of its safety profile proven by various studies. It is less potent and onset of action is slightly prolonged when compared to bupivacaine or levobupivacaine. Use of adjuvants along with local anaesthetic reduces the total dose of local anaesthetic that is required for providing effective labour analgesia. Clonidine is a centrally acting partial alpha 2 adrenergic agonist that reduces the anaesthetic and analgesic requirement of local anaesthetic. This study is aimed to study the effect of ropivacaine with clonidine as an adjuvant for labour analgesia.

Objective: To compare the time of onset of analgesia, total dose of local anaesthetic required, total duration of analgesia and neonatal outcome between the two groups, Group I with ropivacaine and Group II ropivacaine with clonidine.

Materials and Method: A prospective randomised controlled study was conducted in a government peripheral medical College after getting ethical committee clearance 100 patrurients randomised into two groups, Group I received 2% ropivacaine and Group II received 2% ropivacaine with 40 micrograms of clonidine.

Statistical Analysis: The results were analysed with SPSSVersion 13 using student t - test and chi square test

Results: The mean age was 23.4 ±1.7 years. The mean onset time of Group A and Group B were 12.9±1.3 minutes and 17.7±1.3 minutes with p<0.001 which was significant. Total mean dose of Ropivacaine for both groups were 44.0±8.8 and 54.0±8.9 respectively with P <0.05. Neonatal outcome as measured using APGAR score were 8.5±0.5 and 8.4±0.5 being statistically insignificant.

Conclusion: Addition of 40 micrograms of clonidine with Ropivacaine epidurally resulted in rapid onset of analgesia with required dose of Ropivacaine. Use of Clonidine as adjuvant didn't produce any undesirable motor blockade or neonatal depression.

1. Introduction

Labour pain which is the worst pain experienced results in a maternal stress response which is not beneficial to

* *Corresponding author*.
E-mail address: drkanchanamala@yahoo.com (V. J. Karthik).

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the mother or the foetus.[1] Epidural Labour analgesia provides an excellent pain relief for patrurients, better neonatal outcome and a less stress response to mother so that she can feed her newborn as early as possible. Ropivacaine is considered the local anaesthetic of choice for labour analgesia. The addition of adjuvants has proven to significantly reduce the dose of local anaesthetic required for producing effective pain relief without affecting the progress of labour or the fetal outcome.

The mother is ambulant with ambulant with preservation of somatic sensation and has better satisfaction.[2] Alpha 2 agonists[3,4] and opioids as adjuvants help to get excellent pain relief with a low concentration of local anaesthetic. Clonidine as adjuvant[5,6] improves the quality of anaesthesia, reducing the dose of local anaesthetic with better hemodynamic stability, not compromising the fetus or maternal outcome. Clonidine is recommended for routine use in labour analgesia[7] with out adverse neonatal outcome. Our study was designed to compare the effect of clonidine as an adjunct with ropivacaine along with ropivacaine only in providing safe and effective labour analgesia and neonatal outcomes.[8,9]

2. Aim

To compare Ropivacaine 0.2% with or without clonidine in epidural labour analgesia.

3. Objectives

The following are compared in two groups:

1. Time of onset of analgesia
2. Total dose of local anaesthetic required
3. Total duration of labour
4. Neonatal outcome

4. Materials and Methods

4.1. Study design

Prospective randomised controlled study.

4.2. Study population

Patrurients admitted in labour ward of a government peripheral medical College hospital.

4.3. Sample size

5. Patrurients

Selection of patients: The patrurients were randomised by simple random allocation into two groups. Group A received 2% Ropivacaine and Group B received 2% Ropivacaine with 40 micrograms of clonidine for epidural labour analgesia.

5.1. Inclusion criteria

1. Age 18-35 years
2. ASA II patrurients in labour
3. Singleton pregnancy
4. Vertex presentation
5. No other comorbid conditions
6. Patrurients consenting for labour analgesia

5.2. Exclusion criteria

1. Age > 35 years and less than 18 years
2. Multiple pregnancy
3. Comorbid conditions
4. Local sepsis
5. Altered coagulation profile
6. Bleeding diathesis
7. Musculoskeletal disorders
8. Spinal abnormalities
9. H/O allergy to local anaesthetic

5.3. Preparation and technique

The goals of the study and consequences were explained and informed consent was obtained from all the participants. Brief clinical history, age, height, body weight, airway examination, complete general and systemic examination, investigations such as complete blood count, bleeding time, clotting time, FHR examination were done in all patients.

The procedure was carried out in the operation theatre where facilities for resuscitation were available. 18 gauge IV line secured and monitors attached such as ECG, non-invasive blood pressure and pulse oximeter. Baselines PR, SBP, DBP, and SPO2 were recorded. The drugs to be administered epidurally were prepared and stored in a sterile container.

Preloading was done with 500ml Ringer lactate and then i.v infusion given at the rate of 100ml/hour.

The appropriate area was prepared with antiseptic solution (10% Povidone-Iodine solution) and sterile drapes were used to provide maximum barrier precautions during the procedure.

An epidural 16G Tuohy needle was inserted in L3-L4 interspinal space whichever is wider in standard midline or paramedian technique. Epidural space was identified by LOR technique with air. Epidural catheter inserted 5cm cephalad. Test dose was given with 3ml of 1.5% Lignocaine with 5mcg/ml adrenaline to rule out intrathecal and intravascular injection. Adrenaline test dose injected when mother was free of labour pain. The catheter was tapped firmly to the back.

Patients were selected in a randomized order into Group A where Parturients are administered with 10ml of 0.2% Ropivacaine with clonidine 0.4 mcg/kg in divided doses. Subsequent doses were given using 0.2% Ropivacaine and in Group B, Parturients are administered with 10ml of 0.2%

Ropivacaine alone. Paturients not experiencing adequate analgesia in 20 min are supplemented with additional 5 to 10ml of 0.2% Ropivacaine.

Hypotension if occurs, was managed with ephedrine. With the catheter in place patients were shifted to the labour ward, where they were closely monitored till delivery.

Epidural top-ups were given when parturient complained of pain or every hourly till the delivery. Maintenance dose of local anaesthetic were given.

Any breakthrough pain (VAS >4) was managed with 5-10 ml of drug.

The procedure was clearly explained to the patient. The visual analogue pain scale was shown to them and interpretation of the scale explained in detail.

5.4. Statistical analysis

The study subjects were described and compared between the two groups by percentages and averages. The continuous variables were compared between the groups by student independent —t test. The categorical variables were compared between the groups by an appropriate non parametric test namely χ^2 (Chi-square) test. The above statistical procedures were under taken with the help of the statistical package namely IBM SPSS statistics-20. The P-values less than or equal to 0.05 (P≤0.05) were treated as statistically significant.

6. Results

6.1. Demographic profile

Table 1: Comparison of ages between the two groups A&B

Age group	Group A Frequency	%	Group B Frequency	%
20-24	37	74.0	35	70.0
25-29	13	26.0	15	30.0
Total	50	100.0	50	100.0
Mean± SD	23.4±1.7		23.4±1.8	
Significance			"t"=0.112, df= 98, P=0.911	

Table 2: Comparison of height between the two groups A & B

Height (cm)	Group A Frequency	%	Group B Frequency	%
150-155	34	68.0	33	66.0
155-160	16	32.0	17	34.0
Total	50	100.0	50	100.0
Mean± SD	153.5±2.5		153.7±2.4	
Significance	"t"=0.326, df= 98, P=0.745			

Table 3: Comparison of weights between the two groups

Weight (Kg)	Group A Frequency	%	Group B Frequency	%
50-55	16	32.0	15	30.0
55-60	28	56.0	26	52.0
60-65	5	10.0	6	12.0
65-70	1	2.0	3	6.0
Total	50	100.0	50	100.0
Mean± SD	56.4±3.3		56.9±4.0	
Significance	"t"=0.735, df= 98, P=0.464			

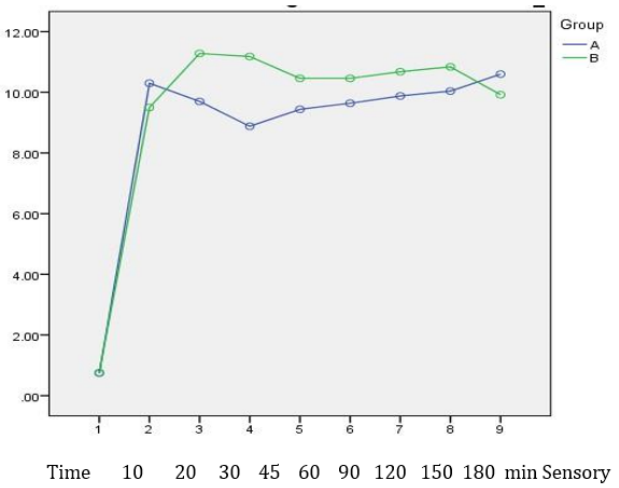

Fig. 1: Comparison of sensory from 10 min through 180 minutes

Demographic variables were comparable between the two groups. There was no significant difference between hemodynamic variables of PR, Systolic and diastolic blood pressure, Spo2 from baseline till 180 minutes between the two groups. Cervical dilatation and heart rate were also comparable between the two groups. Onset of block was significantly reduced in Group A compared to Group B. Additional doses at 1,2,3, hrs and total dose of drug administered were also reduced in Group A compared to B which was statistically significant.

7. Discussion

The primary aim of epidural analgesia is to provide complete pain relief without neonatal compromise which is easily possible with the use of local anaesthetics with adjuvants, Ropivacaine has better cardioprotective and less neurotoxic effect,[10,11] Clonidine is an alpha 2adrenergic receptors in dorsal horn to reduce afferent pain transmission in nuleus tractus solitarii(NTS), exciting a pathway that inhibit excitatory cardiovascular neurons. It also has alpha antagonist effect in posterior hypothalamus and medulla resulting in reduced sympathetic outflow from central nervous system thereby reducing arterial

Table 4: Comparison of pulse rate trends from baseline through 180 minutes

Pulse rate	Group A		Group B		Difference b/w means	"t"	df	Significance
	Mean	SD	Mean	SD				
Base	104.1	7.2	104.6	7.9	0.5	0.345	98	P=0.731
5 Min	105.8	4.9	102.3	8.1	3.5	2.599	98	P=0.011
10 Min	94.3	6.6	96.7	7.2	2.4	1.718	98	P=0.089
20 Min	90.7	8.1	91.6	7.7	0.9	0.556	98	P=0.580
30 Min	87.1	8.5	90.5	9.2	3.4	1.933	98	P=0.056
45 Min	86.3	9.2	89.9	8.5	3.6	2.007	98	P=0.048
60 Min	88.7	9.7	89.8	9.4	1.1	0.554	98	P=0.581
90 Min	88.1	9.6	86.4	8.6	1.7	0.935	98	P=0.352
120 Min	87.3	8.6	87.5	8.2	0.2	0.131	98	P=0.896
150 Min	86.8	8.2	87.4	8.6	0.6	0.321	98	P=0.749
180 Min	87.2	8.1	86.7	9.1	0.5	0.255	98	P=0.799

Table 5: Comparison of systolic BP (SBP) trends from baseline through 180 minutes

SBP	Group A		Group B		Difference b/w means	"t"	df	Significance
	Mean	SD	Mean	SD				
Base	113.7	6.7	115.1	6.0	1.4	1.111	98	P=0.269
5 Min	110.9	6.1	113.3	5.7	2.5	2.089	98	P=0.039
10 Min	106.2	5.2	109.2	5.5	3.0	2.727	98	P=0.008
20 Min	103.3	4.2	108.0	6.0	4.7	4.608	98	P<0.001
30 Min	105.0	4.1	108.4	5.9	3.4	3.276	98	P=0.001
45 Min	106.1	4.9	107.7	5.4	1.6	1.564	98	P=0.121
60 Min	106.5	5.2	108.5	5.7	2.0	1.784	98	P=0.078
90 Min	107.0	4.4	108.3	5.8	1.3	1.261	98	P=0.210
120 Min	107.8	6.2	109.3	6.3	1.5	1.204	98	P=0.231
150 Min	109.9	6.6	108.5	6.3	1.4	1.049	98	P=0.297
180 Min	108.7	5.9	109.4	5.4	0.7	0.672	98	P=0.503

Table 6: Comparison of diastolic BP (DBP) trends from baseline through 180 min

DBP	Group A		Group B		Difference b/w means	"t"	df	Significance
	Mean	SD	Mean	SD				
Base	75.8	3.9	75.6	3.7	0.2	0.368	98	P=0.714
5 Min	74.2	3.8	76.3	3.8	2.1	2.791	98	P=0.006
10 Min	71.4	4.0	74.9	4.0	3.5	4.326	98	P<0.001
20 Min	71.7	3.6	75.2	4.4	3.5	4.280	98	P<0.001
30 Min	72.5	3.9	75.0	4.0	2.5	3.141	98	P=0.002
45 Min	73.1	4.1	74.7	3.9	1.6	1.980	98	P=0.050
60 Min	73.6	3.7	74.7	4.0	1.1	1.337	98	P=0.184
90 Min	74.6	4.1	73.9	3.3	0.7	0.891	98	P=0.375
120 Min	73.9	4.3	73.9	3.0	0.0	0.000	98	P=1.000
150 Min	74.8	4.4	74.0	3.1	0.8	0.988	98	P=0.326
180 Min	74.2	4.3	74.5	3.7	0.3	0.326	98	P=0.745

blood pressure. Epidural clonidine stimulates alpha 2 receptor transmission through non opiod mechanism,[12,13] also causes local vasoconstriction limiting vascular removal of local anaesthetic. Addition of clonidine helps to use dilute solutions of ropivacaine for better analgesia with reduced risk of systemic toxicity and incidence of motor block.[14,15] In this study, 0.2% Ropivacaine with Clonidine and 0.2%ropivacaine alone were compared for labour analgesia with regard to onset of action, total dose of local anaesthetic required, neonatal outcome and pain score in 100 mothers by randomizing them into one of the two groups, the, 0.2% Ropivacaine with Clonidine (A) and the 0.2% ropivacaine alone (B). We observed that patients who received ropivacaine with clonidine had faster onset of analgesia, longer duration of block, less number of top ups compared to those with ropivacaine without clonidine. Similar results were reported by Ahirwar et al[16] and Landav et al[5] and Syal et al[7] reported reduction in onset of analgesia which was observed in our study also.

Table 7: Comparison of SPO_2 trends from baseline through 180 minutes

SPO_2	Group A		Group B		Difference b/w means	"t"	df	Significance
	Mean	SD	Mean	SD				
Base	98.5	0.7	98.6	0.6	0.1	0.910	98	P=0.365
5 Min	98.5	0.7	98.6	0.6	0.1	0.606	98	P=0.546
10 Min	98.5	0.6	98.6	0.6	0.1	0.798	98	P=0.427
20 Min	98.5	0.7	98.5	0.6	0.04	0.302	98	P=0.763
30 Min	98.5	0.7	98.5	0.6	0.0	0.000	98	P=1.000
45 Min	98.5	0.7	98.5	0.6	0.02	0.148	98	P=0.883
60 Min	98.5	0.7	98.5	0.6	0.02	0.148	98	P=0.883
90 Min	98.6	0.5	98.5	0.6	0.1	0.168	98	P=0.867
120 Min	98.5	0.6	98.6	0.6	0.1	0.337	98	P=0.737
150 Min	98.6	0.5	98.6	0.5	0.0	0.000	98	P=1.000
180 Min	98.6	0.6	98.6	0.5	0.04	0.377	98	P=0.707

Table 8: Comparison of cervical dilatation at baseline and at 180 minutes

Cervical dilatation	Group A		Group B		Difference b/w means	"t"	df	Significance
	Mean	SD	Mean	SD				
Base	4.1	0.6	4.3	0.4	0.2	1.728	98	P=0.087
120 Min	6.4	0.9	6.6	0.8	0.2	0.814	98	P=0.418
180 Min	8.4	1.1	8.5	0.9	0.1	0.515	98	P=0.608

Table 9: Comparison of VAS from baseline through 180 minutes

VAS	Group A		Group B		Difference b/w means	"t"	df	Significance
	Mean	SD	Mean	SD				
Base	6.5	0.7	6.9	0.8	0.4	2.537	98	P=0.013
5 Min	6.5	0.7	6.9	0.8	0.4	2.670	98	P=0.009
10 Min	6.2	0.8	6.9	0.8	0.7	4.314	98	P<0.001
20 Min	3.3	1.0	3.7	1.1	0.4	2.174	98	P=0.032
30 Min	1.5	1.3	1.3	1.1	0.2	0.510	98	P=0.611
45 Min	0.5	0.9	1.0	0.9	0.5	2.602	98	P=0.011
60 Min	0.6	0.9	0.9	0.9	0.3	1.860	98	P=0.066
90 Min	1.0	1.1	0.9	1.1	0.1	0.480	98	P=0.633
120 Min	1.0	1.1	1.0	1.0	0.0	0.000	98	P=0.924
150 Min	0.8	1.0	1.1	1.0	0.3	1.390	98	P=0.168
180 Min	0.9	1.0	0.9	1.0	0.02	0.098	98	P=0.922

Table 10: Comparison of FHR from baseline through 180 minutes

FHR	Group A		Group B		Difference b/w means	"t"	df	Significance
	Mean	SD	Mean	SD				
Base	132.7	8.1	132.8	8.4	0.1	0.024	98	P=0.981
5 Min	133.8	8.5	132.1	8.2	1.7	1.031	98	P=0.305
10 Min	131.2	8.6	132.2	8.5	1.0	0.574	98	P=0.567
20 Min	130.8	8.6	133.1	7.4	2.3	1.476	98	P=0.143
30 Min	132.1	7.6	133.1	6.0	1.0	0.774	98	P=0.441
45 Min	130.6	8.8	132.0	5.1	1.4	0.989	98	P=0.325
60 Min	129.6	8.3	133.6	5.3	4.0	2.745	98	P=0.007
90 Min	130.2	8.1	133.5	5.3	3.3	2.440	98	P=0.016
120 Min	130.6	8.0	134.2	6.2	3.6	2.544	98	P=0.013
150 Min	131.6	8.6	133.5	6.8	1.9	1.216	98	P=0.227
180 Min	131.9	8.3	134.4	6.2	2.5	1.664	98	P=0.099

Table 11: Additional doses added at 60 minutes, 120 minutes and 180 minutes

Additional doses at	Group -A		Group-B		Difference b/w means	"t"	df	Significant
	Mean	SD	Mean	SD				
1 hour	11.3	2.2	16.0	3.2	4.7	8.549	98	P<0.001
2 hours	10.6	1.6	12.2	2.7	1.6	3.578	98	P<0.001
3 hours	11.8	2.4	13.0	3.0	1.2	2.186	98	P<0.001

Table 12: Total doses at administered at 1, 2and 3 hours

Total doses at	Group -A		Group-B		Difference b/w means	"t"	df	Significant
	Mean	SD	Mean	SD				
1 hour	11.3	2.2	16.0	3.2	4.7	8.549	98	P<0.001
2 hours	21.9	2.8	28.2	3.5	6.3	9.948	98	P<0.001
3 hours	33.7	3.2	41.4	4.1	7.7	10.60 1	98	P<0.001

Table 13: Comparison of first, second, third stages and total duration

Stages	Group -A		Group-B		Difference b/w means	"t"	df	Significant
	Mean	SD	Mean	SD				
First	226.7	39.1	233.4	34.6	6.7	0.910	98	P=0.365
Second	21.4	4.3	23.0	4.8	1.6	1.757	98	P=0.082
Third	8.0	2.1	7.4	1.9	0.6	1.536	98	P=0.128
Tot duration	256.2	38.2	263.9	35.1	7.7	1.049	98	P=0.297

Table 14: Comparison of APGAR and Total LA between the two groups

Others	Group -A		Group-B		Difference b/w means	"t"	df	Significant
	Mean	SD	Mean	SD				
APGAR	8.5	0.5	8.4	0.5	0.04	0.396	98	P=0.396
Total LA	44.0	8.8	54.0	8.9	10.0	5.641	98	P<0.001

Table 15: Comparison of onset time between the two groups

Onset time	Group- A		Group-B	
	Frequency	%	Frequency	%
10-15	44	88.0	1	2.0
15-20	6	12.0	49	98.0
Total	50	100.0	50	100.0
Mean± SD	12.9±1.3		17.7±1.3	
Significance	"t"=17.812, df= 98, P<0.001			

8. Conclusion

Administration of 0.2% Ropivacaine with addition of Clonidine epidurally not only improves the onset of analgesia, but also reduces the total anaesthetic requirement. The addition of this dose of Clonidine does not result in any significant increase in the incidence of undesirable motor blockade or neonatal depression when compared to Ropivacaine alone.

9. Limitation of Study

In this study the parity of the mother was not taken into account while observing the duration of labor.

Duration of first and second stage of laborvaries with parity. Multiparous women progress faster compared to a primigravida. Hence, error might have occurred during comparison of duration.

10. Source of Funding

None.

11. Conflict of Interest

None.

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Author biography

B Kanchanamala, Associate Professor

V J Karthik, Associate Professor

N Keerthana, Assistant Professor

C Kokila, Assistant Professor

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