The Journal of Medical Research

Research Article

JMR 2015; 1(5): 148-151
September- October
ISSN: 2395-7565

www.medicinearticle.com

Comparison of epidural Butorphenol-ropivacaineand Fentanyl-ropivacaine for labour analgesia-Randomized Double Blind Study

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Abstract

Background: Advancement in labour analgesia includes newer local anaesthetics with more selective sensory blockade which permit ambulation of parturient, various technological improvement and newer adjutant which facilitate reduced requirement of local anaesthetics and hence side effect. **Objective:** The objective of this study was to evaluate the efficacy butorphenol 0.5mg and fentanyl 25 mcg mixed with 0.1% ropivacaine for epidural labour analgesia. **Material and Method:** After Institutional Ethical approval and written informed consent, 60 full term parturient with spontaneous onset of labour randomly assigned to two equal groups of 30 each, to receive an epidural injection of 12 ml ropivacaine 0.1% with butorphenol 0.5ml (500 mcg) in group B1 and 12 ml of ropivacaine 0.1% with fentanyl 0.5ml (25 mcg) in group L2 as initial bolus dose. Further Top-up of 0.1% ropivacaine was given on patients demand. Duration of analgesia, sedation, hemodynamic parameters, oxygen saturation, Respiratory rate, foetal Apgar score and maternal side effect were compared. Results were analysed by oneway analysis of variance test, Fisher's exact test or Chi Square test, whichever appropriate. **Result:** Demographic data and obstetrical characteristics were comparable between two groups. After initial epidural bolus, duration of analgesia was significantly more in group B (90.70±41.21) than in group R (62.80±34.12) ($p<0.001$). Hemodynamic parameters, VAS Score and side effects were comparable between two groups. Neonatal outcome (Apgar score) was also comparable between two groups. **Conclusion:** Epidural ropivacaine 0.1% with butorphenol or fentanyl results in satisfactory labour analgesia without any increase in side effects. Duration of analgesia was more in butorphenol group.

Keywords: Labour analgesia, Ropivacaine, Butorphenol, Fentanyl.

INTRODUCTION

In the field of labour analgesia a long journey had taken place from era of ether and chloroform to modern evidence based programmed labour pain management. Recent advancement includes combined spinal epidurals, low-dose epidurals facilitating ambulation and intravenous or epidural Patient Controlled Analgesia (PCA). The main goals of labour analgesia are pain relief without affecting progress of labour, foetal well-being and maternal safety.

Lumbar epidural is the most commonly used technique due to its flexibility of as required bolus drug administration, minimal hemodynamic alteration and its safety in labour parturient. After bolus dose, maintenance of analgesia is achieved by intermittent boluses, continuous epidural infusion or patient controlled epidural analgesia. However, hypotension or motor block may be distressing to parturient mother due to sympathetic blockade by high dose of local anaesthetics. Opioids are the time honoured drugs which have been used as adjutant in epidural to reduce the unwanted side effect of local anaesthetics but they increases risk of nausea, vomiting, pruritus, respiratory distress and foetal distress [1, 2]. Butorphenol belong to phenanthrene group of agonist- antagonists, having agonist action on kappa receptor and antagonist or partial agonist activity on mu receptor. Fentanyl is well studied and widely used for labour analgesia. So this study was designed to compare the pain relief and complications of epidural Butorphenol with fentanyl in labour analgesia.

MATERIAL AND METHODS

After Institutional Ethical approval and written informed consent, 60 full term parturient of ASA grade I & II with spontaneous onset of labour were included in this prospective, randomized, doubleblind trial. Parturient with cephalo-pelvic disproportion (CPD), contracted pelvis, pregnancy induced hypertension (PIH), active phase of labour, foetal distress, coagulopathy, hypersensitivity to local anesthetics or studied

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drugs and any contraindication to epidural anesthesia were excluded from the study.

In sitting position after all aseptic precaution, 18G Epidural needle was introduced in L3-L4 interspace. After confirmation of correct position of needle by loss of resistance technique, epidural catheter was advanced into epidural space and secured at desired length. Test dose (3ml) of xylocaine with adrenaline (1:200,000) was administered to rule out intravascular placement of epidural catheter. Patient was placed in supine position if there were no significant changes in heart rate or electrocardiogram 3 minute after drug administration. When labour was well established, allocated drugs were given to respective group. On patient demand Top-up of ropivacaine 0.1% was given.

All patients were randomized (computer generated randomization and concealment via sealed opaque envelope technique) into two equal groups (n=30):Group B: To receive 0.5 mg (0.5 mL) Butorphenol plus 11.5 mL of 0.1% ropivacaine through epidural catheter and Group L:to receive 25 mcg (0.5 mL) fentanyl with11.5 mL of 0.1% ropivacaine through epidural catheter. Total volume in both group were 12ml.

Onset and duration of analgesia, sedation, sensory and motor block, hemodynamic parameters, oxygen saturation and Respiratory rate were recorded at 15, 30, 60, 120, 150, 180 minutes after injection. In addition to above readings foetal heart rate (FHR), foetal heart sound (FHS) by cardiotocography and uterine contraction were recorded at regular intervals. The occurrence of maternal side effect such as pruritus, hypotension, nausea and vomiting were recorded. Mode of delivery, foetal APGAR score at 1 and 5 minute interval, foetal cord blood analysis was recorded after vaginal delivery.

Pain was assessed by VAS (0-10) on which 0 indicates "no pain", 1-3 mild pain, 4-7 moderate pain and 7-10 severe pain.The sedation score was assessed using the Ramsay sedation score: 1 = anxious or restless, 2 = cooperative and oriented, 3 = asleep and responding to commands, 4 = asleep but strong response to stimulus, 5 = sluggish response to stimulus and 6 = no response to stimulus.

Statistical analysis

The sample size was calculated by power and sample size calculator. To detect a 20% difference in the primary outcome between the compared groups with a standard deviation of 25% (estimated from initial pilot observations), 80% power and 5% alpha error; a sample size of 26 per group was required. We selected 30 patients per group to compensate for dropouts.

The statistical analysis was performed with SPSS Statistics for Windows, Version 16.0. The continuous variables were compared by one way analysis of variance test. Discrete variables were compared by Fisher's exact test or Chi Square test, whichever appropriate. $P < 0.05$ was considered significant.

RESULT

There was no significant difference between two groups regarding demographic data and obstetrical characteristics (Table 1).

Mean VAS score before administration of epidural drugs was 9.64±0.76 in group B and 9.84±0.56 in group (p>0.05) (Table 2). In both group effective analgesia (VAS<3) was achieved after single bolus dose, 17.34 ±4.86 minute in group B, 15.16±5.12 minutes in group R and comparable (p>0.05). Duration of analgesia after initial bolus dose was significantly more in group B (90.70±41.21) than in group R (62.80±34.12) (p<0.001) (Table 2). No significant difference in VAS scores in both groups was observed up to 30 minutes. Thus Group B patients were experiencing longer duration of pain relief than Group L and the requirement of top up was more in Group L.

There was no significant difference in HR, RR, NIBP and SpO_2 in both the groups in different time interval. Haemodynamic statuses of parturient in both groups were comparable. None of the patients in any group required either ephedrine or atropine (Table 3)

The incidence of maternal complication like nausea, vomiting was identical in both the groups, two patients in each Group. The incidence of pruritus was more in Group L than Group B (Table4). None of the patients had headache, urinary retention and respiratory depression. One patient needed LSCS delivery from Group B and two patients from Group L. None of the parturient has forceps delivery in either group.

Neonatal outcome was favourable in both the groups (Apgar scores >7 at 1 and 5 min) with no side-effects. Foetal cord blood gas analysis was also same in both the groups.

Table 1: Demographic Data, obstetrical characteristicsand Baseline Parameter (Mean± S.D)

S. No	Parameter	Group B	Group L	P- Value
1.	Age (year)	28.34±2.12	27.89±2.32	>0.05
2.	Weight (Kg)	69.26±3.67	70.64±4.42	>0.05
3.	Gestation (wks.)	38.8	39.1	>0.05
4.	Cervical Dilatation	3.7	3.5	>0.05
5.	Parity (primi/second)	18/12	20/10	>0.05

All values expressed as mean±SD. No significant difference between two groups. SD= Standard deviation

Table 2: Efficacy of Analgesia(Mean±S.D)

S. No.	Parameter	Group B	Group L	P-Value
1.	Onset of Analgesia (min.)	17.34 ±4.86	15.16±5.12	>0.05
2.	Duration of Analgesia	90.70±41.21	62.80±34.12	<0.001
2.	VAS Score			
	Before bolus dose	9.64±0.76	9.84±0.56	>0.05
	5 min after bolus dose	4.12±1.86	4.86±1.62	>0.05
	15 min after bolus dose	0.13±.68	0.24±0.34	>0.05
	30 min after bolus dose	0.00±0.00	0.00±0.00	>0.05
4.	Mean time to first top-up(min.)*	84.26±16.28	54.15±14.42	

* Time of bolus dose to time to achieve VAS<3, VAS: Visual analogue scale, SD=Standard deviation. SD= Standard deviation

Table 3: Hemodynamic Parameter, Oxygen Saturation and Respiratory Rate (Mean±S.D)

S. No.	Parameter	Group B	Group L	P- Value
1.	Baseline Heart Rate(per min)	78.58±7.86	77.34±6.94	>0.05
2.	Lowest Heart Rate (per min)	73.24±6.45	72.67±5.84	>0.05
3.	Baseline MAP (mmHg)	84.46±7.43	86.40±7.12	>0.05
4.	Lowest MAP (mmHg)	76.86±6.86	75.43±5.75	>0.05
5.	Oxygen Saturation (SpO2)	97.40±1.14	97.80±0.89	>0.05
6.	Respiratory Rate (RR)	15.60±1.13	14.75±1.25	>0.05

MAP: Mean arterial pressure, SD: Standard deviation

Table 4: Adverse Effects (No of patient)

S. No	Parameter	Group B	Group L
1.	Hypotension	0	0
2.	Pruritus	0	1
3.	Nausea/Vomiting	2	2
4.	Sedation	1	0
5.	Somnolence	0	0

DISCUSSION

In the present study, epidural labour analgesia with ropivacaine 0.1% combined with Butorphenol or Fentanyl produce satisfactory labour analgesia in both group, however we observed prolong duration of analgesia in butorphenol group without any unwanted side effects. Newer local anaesthetic ropivacaine have reduced systemic toxicity and preferentially more sensory blockade than motor especially at lower concentration [3]. So ropivacaine is preferred now days due to increase demand of ambulatory labour analgesia. Various study demonstrated that 0.1% ropivacaine is as effective as 0.2%, if opioid are added to 0.1% solution [4-6].

We observed no difference in duration of onset of analgesia in both group but total duration of analgesia after initial bolus dose was significantly more in butorphenol group than fentanyl group. Prakash *et al* [7] and Hund *et al* [8] used 2 mg and 3 mg butorphenol respectively and observed that duration of analgesia increases with the use of butorphenol. We observed slight fall in MAP and heart rate from baseline value but none of parturient required treatment for hypotension and bradycardia. There was no decrease in RR, SpO_2 and NIBP in both the groups at different intervals. Porter *et al* [9] reported that maternal oxygen desaturation (<95%) was observed with high dose of opioids. The mean oxygen saturation was better in our study in both the groups.

In our study, maternal expulsive effort, instrumental delivery, and neonatal status were comparable in both groups as observed by others. [10, 11]There was no difference between APGAR scores of both the groups at 1 and 5 minutes interval. Foetal cord blood gas analysis is similar to study done by others. [8]

Incidence of maternal complication, nausea and vomiting was not significant two from each group B and group L. Pruritus appeared in group Lonly and none from group B. Hund et al[8]reported somnolence in two patients out of 22 who had received 2 mg of butorphenol. The incidence of somnolence was dose related and it occurred more with increasing dose of butorphenol. None of the patients in any group reported such as headache, retention of urine which is similar to other study. In our study one patient was sedated in group B similar to study done by Kumar et al concluded that more patients were sedated in butorphenol groups than fentanyl.

Main two limitation of our study was smaller sample size and intermittent bolus technique. Lager sample size may give more precise result of analgesia and side effects. Similarly continuous infusion technique gives a better estimation of drug requirement.

CONCLUSION

We conclude that low dose epidural ropivacaine 0.1% with butorphenol or fentanyl results in satisfactory labour analgesia with ambulation without any increase in side effects. Ropivacaine with butorphenol had longer duration of analgesia and require less top-up than ropivacaine with fentanyl. Hence our study favours the use of ropivacaine with butorphenol for labour analgesia.

Conflicts of interests

None declared.

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