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Epidural Labour Analgesia What's New: Comparison of 0.125% Ropivacaine-Dexmedetomidine versus 0.125% Levobupivacaine-dexmedetomidine

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Abstract: ***Background: Levobupivacine and Ropivacaine are newer local anaesthetics with effects similar to bupivacaine but with the advantages of reduced central nervous system and cardiovascular toxicity. The aim of this prospective study was to compare ropivacaine and levobupivacaine with dexmedetomidine as adjuvantwith both, for epidural analgesia in labour regarding onset, quality, duration of analgesia, motor blockade, labour outcome and any adverse effect on foetus. Methods: Fifty parturients were randomly divided into two groups comprising of 25 partuients each. The patients in group I received 10 ml of 0.125% ropivacaine with dexmedetomidine (0.5µg/kg) as initial dose and 8 ml of 0.125% ropivacaine with 0.5µg/kg of dexmedetomidine as subsequent top up doses as and when required. Patients in group II recieved10 ml of 0.125% levobupivacaine with dexmedetomidine (0.5µg/kg) as initial dose and 8 ml of 0.125% levobupivacaine with dexmedetomidine (0.5µg/kg) as subsequent top up doses as and when required. The onset, duration and quality of analgesia, motor blockade and feto-maternal outcomes were studied. Results: All parturient had effective labour analgesia with no motor blockade observed in both the groups. Onset of analgesia was significantly faster (p=.022) in group II (levobupivacaine + dexmedetomidine) as compared to group I (ropivacaine + dexmedetomidine) with the mean time of onset of analgesia being 12.24±1.30 minutes in group I (ropivacaine + dexmedetomidine) and 11.16±1.86 minutes in group II (levobupivacaine +dexmedetomidine).Mean VAS score were significantly less (p=0.046) in group II in 5, 10and 15 min. p value <0.05. The total duration of analgesia following the initial dose was 172.16±21.25 minutes whereas in group I, the mean duration of analgesia was 158.52±25.58 minutes. There was no significant difference in relation to motor blokcade, mode of delivery or fetal outcomes. Conclusion: We conclude that both the concentrations of levobupivacaine and ropivacaine along with adjuvant dexmeditomidine, both provide effective labour analgesia. However, levobupivacane was found superior in terms of faster onset, prolonged duration of action, lesser incidence of breakthrough pain requiring lesser top-ups, and hence a lesser consumption of drugs***

Keywords: ropivacaine, levobupivacaine, dexmedetomidine, labour epidural analgesia

1. Introduction

Central neuraxial analgesia is the most versatile method for providing labour analgesia and is currently the gold standard technique for pain control in obstetrics.[1]Levobupivacaine and ropivacaine are newer local anesthetics that have effects similar to bupivacaine.[2-4]In the context of labour analgesia, the lesser degree of motor blockade from both these drugs is another advantage compared to bupivacaine. The utilization of lower concentrations of local annaesthetics along with various adjuvants provides good analgesia with a lower incidence of motor blockade and therefore, a lower incidence of instrumental delivery.

Therefore, we designed the present study to evaluate and compare the quality and duration of epidural analgesia of ropivacaine and levobupivacaine along with dexmedetomidine as adjuvantin labouring parturients. The primary outcome of the study was onset and duration of analgesia whiles the secondary outcome being incidence of motor blockade, labour outcome and any adverse effect on foetus.

2. Material and Methods

Once approval by the institution clinical research (Ethical) committee has been obtained, 50 parturients who requested labour epidural analgesia and were carrying singleton pregnancies of 36 weeks or greater gestation, in active labour, with contractions at every 5 minutes at least, were enrolled into this study.

Sample Size: A power calculation for this study was difficult because of the many outcomes under consideration. However, we used means-effect size for calculating the group sizes, first using the Tstatistic (with non-centrality

parameter), then using the Z statistic. Therefore, we carried out this study in 50 women to achieve a power of 0.8. Group allocation: The 50 parturients were randomly assigned to one of two groups of 25 patients each using the sealed envelope techniques. Group I received 10 ml of 0.125% ropivacaine with dexmedetomidine (0.5µg/kg) as initial dose and 8 ml of 0.125% ropivacaine with 0.5µg/kg of dexmedetomidine subsequent top up doses as and when required. Group II received 10 ml of 0.125% levobupivacaine with dexmedetomidine (0.5µg/kg) as initial dose and 8 ml of 0.125% levobupivacaine with dexmedetomidine (0.5µg/kg) as subsequent top up doses as and when required.

Labor analgesia technique:

A written informed consent was obtained from all the participants. They underwent a detailed pre-anaesthetic checkup and theprocedure and Visual analogue scale (VAS) score was explainedto them prior to the insertion of the epidural catheter. Once the parturient was in active stage of labour, VAS score was noted with VAS 0 = no pain and 10= worst pain along with other baseline parameters including, pulse rate, blood pressure and fetal heart rate as pre labor characteristics. All the parturients were preloaded with 500ml of Ringer lactate prior to insertion of epidural catheter. In left lateral position, understrict aseptic precautions, 18G epidural catheter was inserted in L_{2-3} or L_{3-4} interspace using 18G Tuohy's needle and the loss of resistance to air/water technique. An 18 G multi-orifice catheter was threaded cephalad and fixed such that 4-5cm of catheter remained in the space. A test dose consisting of 3ml xylocaine 2% with adrenaline given to rule out intrathecal or intravenous insertion. Once the test dose was confirmed to be have a negative result, the catheter was secured and the parturient was made supine with left uterine displacement. If any signs of intrathecal or intravenous insertion were noted, the catheter was removed, and the patient was excluded from the study.

Epidural analgesia was initiated once the parturient was having regular contractions with a frequency of at least 1-2 contractions every 3 minutes and pain intensity using Visual Analogue Score of more than 4. Depending upon the randomisation done, the patients received either10mL of 0.125% ropivacaine with dexmedotomidine (5µg/kg) in group I or10ml of 0.125% levobupivacaine with dexmedetomidine in group II.

Pulse, blood pressure and Visual analogue scale (VAS) score were checked prior to injecting drug and then every 5 minutes for the first 30 minutes and then every 15minutes for the first hour and every half hourly thereafter till delivery of placenta. Onset of analgesia was defined as time taken from drug administration to VAS <3. Top up dose of 8 ml was given whenever the VAS score was ≥ 4 after the first dose. If the pain relief was inadequate after 15 min of peak contraction, then that patient was withdrawn from the study. Presence of motor block in the lower extremities was assessed using a Breen modified Brommage scale (BMBS: Grade 1 as complete motor block to Grade 6 as no motor block). Labour was considered completed when spontaneous vertex or assisted vaginal delivery occurred. Labour was managed as per institutional labour ward protocol.

At any point of time during the study period, hypotension was treated with intravenous ephedrine hydrochloride 6 mg. Bradycardia was treated with intravenous bolus of atropine sulfate 0.6mg.

Data Recording

The following parameters were recorded as labor characteristics: onset of analgesia, dermatomal level of analgesia, duration of the epidural analgesia, duration of the first and second stage, total amount of local anesthetic used as top-up bolus doses and their frequency of administration, degree of motor blockade by modified Brommage score and the parturient's complaints if any, after institution of epidural analgesia (including nausea, vomiting, backache and fever).Fetal heart rate, mode of delivery, Apgar scores of the newborn, body weight of the newborn and the presence of postpartum hemorrhage were also noted in both groups.

3. Results

The demographic data of both groups wasstatistically comparable (Table 1).

Table 1: Demographic data

	Group I n=25	Group II n=25	P value
Age, years	24.56±3.47	24.36±3.78	NS
Weight, kg	65.6±7	64.5±6	NS
Height, cm	156±5	156±5	NS
Parity, % Primigravida Multigravida	 56 44	 68 32	 NS NS

Table 2: Labour and pain characteristics

	Group I (n=25)	Group II (n=25)	P Value	
VAS Score (mean ± SD)				
Before bolus dose.	9.84±0.55	10.00±0.00	.155	NS
5 min after bolus dose	6.32±1.4	5.72±1.17	.073	NS
10 min after bolus dose	1.76±0.96	1.16±1.21	.059	NS
15 min after bolus dose	00±00	00±00	00±00	
30 min after bolus dose	00±00	00±00	00±00	
Patient distribution according to time of onset	12.24±1.30	11.16±1.86	.022	S
Duration of analgesia, min	158.52±25.58	172.16±21.25	.046	S
Duration of first stage of labour, min	170.68±148.17	205.12±201.86	0.49	NS
Duration of second stage of labour, min	35.72±14.72	39.84±15.81	0.34	NS
Total duration of labour, min	212.36±154.54	250.36±210.19	0.47	NS
No of top up doses	0 – 3 (0.60±0.91)	0 – 4 (0.60±1.04)	1	NS
Motor blocade	Nil	Nil		

Ns not significant S significant

Demographic data, obstretic data, and other parameters were comparable in both groups P>0.05 (table 1). Before

initiation of labour analgesia, VAS score was 9.84±0.55 in group I and 10.00±0.00 in group II. In both groups, effective analgesia was achieved after the initial bolus dose and the parturients were satisfied with the VAS score decreasing to 0 by15 min after the dose with no failure (Table 2).

The time of onset of analgesia was less in group II (levobupivacaine + dexmedetomidine) as compared to group I (ropivacaine + dexmedetomidine). The mean time of onset of analgesia was 12.24±1.30 minutes in group I (ropivacaine + dexmedetomidine) whereas it was 11.16±1.86 minutes in group II (levobupivacaine + dexmedetomidine). This difference in the time of onset of analgesia was statistically significant ($p<0.05$).

When the VAS Scores in group I and group II were compared, there was no significant difference found at 5, 10 and 15 minutes. The quality of analgesia was also comparable in both the groups.

The total duration of analgesia following the initial dose was statistically significantly (add P value) more with group II when compared to group I. In group II, the mean duration of analgesia was 172.16±21.25 minutes whereas in group I, the mean duration of analgesia was 158.52±25.58 minutes.

The number of top ups required in both the groups was statistically comparable (add p value), varying in the range of 0-3 in group I to 0-4 in group II

The duration of labour was not prolonged in either of the two groups, total duration being 212.36±154.54 minutes in group I and 250.36±210.19 minutes in group II.

No motor blockade was noted in either group.

The hemodynamic parameters (heart rate and blood pressure) were comparable in both the groups before and after initiation of the epidural analgesic.

There was no significant variability in fetal heart rate in either of the groups before and after initiation of the epidural analgesic.

Table 3: Labour characteristics

	Group I (n=25)	Group II (n=25)
Vaginal delivery (%)	92	92
Instrumental delivery	8	8
Newborn weight (kg)	2.80±0.30	2.75±0.21

On comparison of the labour outcome characteristics (Table 3), no statistically significant difference was noted in the mode of delivery, the foetal weight or the APGAR scores at 1 and 5 minutes. None of our patients suffered from postpartum haemorrhage.

4. Discussion

In the presentstudy, epidural analgesia in both the groups produced adequate labour analgesia in all parturients in both the groups with 100 % success rate. However, we observed that the mean time taken for onset of labour analgesia was significantly shorter in patients receiving levobupivacaine in compared with ropivacaine. Peduto et al in 2003 compared epidural levobupivacaine 0.5% and ropivacaine 0.75% and the time taken for sensory blockade was comparable in both the groups.[14]Sah N et al in 2007 compared ropivacaine (0.2%), bupivacaine (0.125%), and levobupivacaine (0.125%) for labour epidural analgesia. Time to onset of sensory analgesia was shorter in the ropivacaine (9.35±4.96) and levobupivacaine (9.56±4.96) groups than bupivacaine (11.89±7.76) group.[15]Possible difference in results can be explained by the higher concentration of ropivacaine as compared to levobupivacaine used in these studies.

The mean duration of analgesia in the present study with the initial bolous dose was longer i.e. 172.16±21.25 minutes in group II as compared to group I (158.52±25.58). Addition of the adjuvant dexmedetomidine leads to a further increase in the duration of analgesia. The requirement for top up doses was less in both groups compared to other studies. Mantauvalou M et al, in 2008, compared 0.5% isobaric bupivacaine, ropivacaine and levobupivacaine for lower abdominal surgery and found that duration of sensory block was significantly shorter in ropivacaine group (220±30min) compared with bupivacaine (237±88min)and levobupivacaine (230±74 min).[16] Senard et al in 2004, compared 0.1% ropivacaine and levobupivacaine (conc?) with morphine for post-operative analgesia (in which pt group). Duration of analgesia was longer in levobupivacaine (328±157) as compared to ropivacaine (302±84).[17]The main undesirable side-effects seen in both the groups were nausea and somnolence were as none of the parturient had Hemodynamic variations in the present study before and after epidural block in both the groups was statistically insignificant.These findings were comparable with that of Hughes *et al*.[18]

None of our patients experienced nausea, vomiting and urinary retention in the peripartum period. There was no motor block in both the groups as per the modified Brommage scale. The neonatal outcomes were comparable with Apgar scores being at least 9/10 at the first minute in both the groups.

We found that the maternal expulsive effort and neonatal status were comparable in both the groups. Epidural analgesia had no statistically significant impact on the incidence and risk of cesarean section, maternal satisfaction with pain relief. As well as neonate's did not appear to have an immediate effect on neonatal status as determined by APGAR scores.

The limitation of this study could be a requirement of a larger sample size which would give a wider perspective on maternal and neonatal size effects.

In conclusion, both levobupivacaine and ropivacaine combined with dexmedetomidine as adjuvant provide effective labour analgesia without jeopardizing the safety of mother and fetus. However, levobupivacaine has faster on set and significantly longer duration of analgesia more compared to ropivacaine with a single dose and required lesser top-ups, resulting in lesser consumption of drugs. Hence, we suggest the use of 0.125% levobupivacaine with

dexmedetomidine for labour analgesia over 0.125% Ropivacaine with dexmedetomidine.

References

[1] Wong C A. Advances in labour analgesia. International Journal of Women's health 2009:139-54.
[2] 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;76:66-71.
[3] Campbell DC, Zwack RM, Crone LA, Yip RW. Ambulatory labor epidural analgesia: bupivacaine versus ropivacaine. Anesth Analg 2000;90:1384-9.
[4] Vercauteren MP, Hans G, De Decker K, Adriaensen HA.Levobupivacaine combined with sufentanil and epinephrine for intrathecal labor analgesia: a comparison with racemic bupivacaine. Anesth Analg 2001;93:996-1000.
[5] Hollmen A, Jouppilla R, Jouppilla P, et al: Effect of extradural analgesia using bupivicaine and2-chloroprocaine on intervillous blood flow during normal labour. *Br J Anaesth*; 1982, 54:837-42.
[6] Halpern SH: Epidural ropivacaine versus bupivacaine for labor: A meta-analysis. *Anesth Analg*;2003, 96:1473-9.
[7] El-Tallawy SN: Fetal Doppler indices during obstetric analgesia. *EJMP*; 2005, 10 (18):47-58.
[8] Benhamou D, Ghosh C, Mercier F: A randomized sequential allocation study to determine the minimum effective analgesic concentration of levobupivacaine and ropivacaine in patients receiving epidural analgesia for labor. *Anesthesiology*; 2003, 99:1383-6.
[9] Grewal A. Dexmedetomidine: New avenues. J Anaesthesiol ClinPharmacol 2011;27:297-302.
[10] Mahendru V, Tewari A, Katyal S, Grewal A, Singh MR, Katyal R. Acomparison of intrathecal dexmedetomidine, clonidine, and fentanyl asadjuvants to hyperbaric bupivacaine for lower limb surgery: A doubleblind controlled study. J Anaesthesiol Clin Pharmacol 2013;29:496-502.
[11] Karaman S, Evren V, Firat V, Cankayali I. The effects of dexmedetomidineon spontaneous contractions of isolated gravid rat myometrium. AdvTher 2006;23:238-43.
[12] Sia AT, Kwek K, Yeo GS. The *in vitro* effects of clonidine anddexmedetomidine on human myometrium. Int J Obstet Anesth2005;14:104-7.
[13] Candiotti KA, Bergese SD, Bokesch PM, Feldman MA, Wisemandle W, Bekker AY, *et al.* Monitored anesthesia care with dexmedetomidine: A prospective, randomized, double-blind, multicenter trial. Anesth Analg 2010;110:47-56.
[14] Peduto VA, Baroncini S, Montanini S, Proietti R, Rosignoli L, Tufano R, et al.A prospective, randomizes, double-blind comparison of epidural levobupivacaine 0.5% with epidural ropivacaine 0.75% for lower limb procedures.Eur J Anaesthesiol 2003;20:979-83.
[15] Sah N, Vallejo M, Phelps A, Finegold H, Mandell G, Ramanathan S.Efficacy of ropivacaine, bupivacaine andlevobupivacaine for labor epidural analgesia.J Clin Anesth.2007;19:214-7
[16] M.Mantouvalou, S.Ralli, H.Arnaoutoglou, G.Tziris, G.Papadopoulos.comparison of plain ropivacaine, bupivacaine and levobupivacaine for lower abdominal surgery.Acta Anaesth.Belg., 2008, 59, 65-71.
[17] Senard M, Kaba A, Jacquemin MJ, Maquoi LM, Geortay MP, Honoré PD et al. Epidural levobupivacaine 0.1% or ropivacaine 0.1% combined with morphine provides comparable analgesia after abdominal surgery. Anesth Analg. 2004;98 (2):389-94.
[18] Hughes D, Hill D, Fee JP. Intrathecal ropivacaine or bupivacaine with fentanyl for labour. Br J Anaesth 2001;87:733-7.