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A Randomised Prospective Comparative Study on Efficacy of Ropivacaine with Fentanyl and Ropivacaine with Clonidine in Labour Analgesia

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Abstract: ***We have performed a randomized, double-blinded comparison of two epidural drug regimens for analgesia in labour. In fentanyl group 40 healthy parturient received 0.2% ropivacaine with fentanyl. In clonidine group 40 healthy parturient received 0.2% ropivacaine with clonidine. Both groups received an initial dose of 10 ml, and top-up dose of 10 ml. The two groups were compared for complete analgesia at 20 min. Hemodynamic changes, height of sensory, patient visual analogue score, mode of delivery, drug dosage requirement, patient assessment of motor blockade. Patient received ropivacaine with fentanyl (median 1.0 Vs. 2.0 p=0.001) is significant. The ropivacaine and fentanyl group was more likely to be pain free in the second stage of labour. There was no significance in patient assessment of motor blockade or mode of delivery between the groups. Pain relief and satisfaction score from patients was consistently better in ropivacaine with fentanyl group.***

Keywords: ropivacaine, fentanyl, clonidine, epidural anaesthesia, second stage of labour

1. Introduction

The pain of childbirth is arguably the most severe pain most women will endure in their lifetime. Since pain relief in labor has always been surrounded with myths and controversies, providing effective and safe analgesia during labor have remained an ongoing challenge. Neuraxial techniques are accepted as the gold standard for intrapartum labor analgesia. Multiple randomized controlled trials comparing epidural analgesia with systemic opioids, nitrous oxide, or both have demonstrated lower maternal pain scores and higher maternal satisfaction with neuraxial analgesia.

First stage of labor

Begins from onset of regular uterine contractions and endsat complete cervical dilatation. Pain is caused by stretchingof the lower uterine segment (LUS) and cervix, whichstimulates the mechanoreceptors. Noxious impulses arecarried by sensory nerve fibres (Aδ and C), which accompanysympathetic nerve endings, travel through paracervical ganglion and hypogastric plexus to the lumbar sympathetic chain which enter the spinal cord at T10, T11, T12 and L1 spinal segments[1]. Pain is visceral in nature i.e. transmitted slowly, poorly localized, primarily in the lower abdomen, also referred to lumbosacral area, gluteal region and thighs.

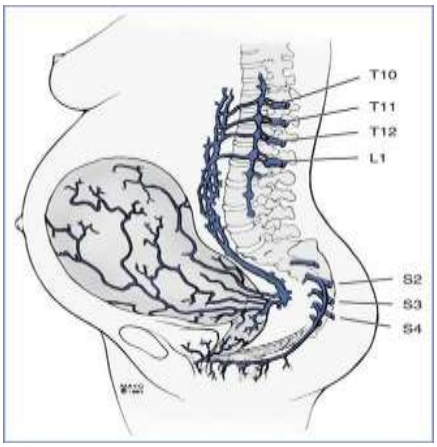

Figure 1

Second stage of labor

Begins from complete cervical dilatation and terminateswith the delivery of the baby. Pain is caused by distensionof pelvic structures and perineum due to descent of thepresenting part, ischemia and frank injury and is carriedby somatic afferent nerve fibers that transmit impulses through pudendal nerve to the spinal cord at S2, S3, and S4levels(figure 1). Typical of somatic pain, it is sharp and well-localized[2].

Ropivacaine has been introduced in clinical practice as it has less motor block than bupivacaine. Adjuvants used opioids and non opioids like clonidine to prevent local anaesthetic dose requirement better quality of analgesia. Clonidine[5] produces analgesia via non opioid mechanism, it does not interfere with proprioception and unlike extradural opioid , it does not produces respiratory depression, nausea, pruritus.it enhances the analgesic effect of local anaesthetic without increasing the side effects.Fentanyl is a highly lipid-soluble

synthetic opioidwith analgesic potency 100-times that of morphineand 800-times that of pethidine[6].

The aim of our study was to see if the addition of small dose of fentanyl, clonidine and ropivacaine mixture improve the duration analgesia[11], reduce the total dose local anaesthetic and adverse effect (motor blockade, nausea, hypotension, pruritus).

2. Methods

The study was approved by hospital ethical committee , after obtaining the informed consent from the patient , We studied 80 women, ASA I & II who were candidates for epidural analgesia . Complicated pregnancy, multi parity were excluded. The parturients were allocated randomly to two equal groups. An extradural catheter was inserted at either L2-L3 or L3-L4 lumbar intervertebral space in sitting position, epidural space identified by loss of resistance syringe with a16 G Tuohy needle inserted at L2-L3 or L3-L4 space with bevel directed cephalade(figure 2) , a three side hole catheter was advanced 3-5 cm through the needle and secured in place.

After test dose of 1.5% Lignocaine 1 ml with adrenaline 5 mcg , an initial volume of 10 ml containing one of the following drug combinations was injected in a double-blind fashion .

Group R1: Ropivacaine0.2% with 37.5 mcg Clonidine

Group R2: Ropivacaine0.2% with 25 mcg Fentanyl

10 ml of drug combination was injected at early stage second stage of labour, the mother lay on supine position with left lateral tilt, 5 min later assessment of the quality of epidural block was made using pain scores and absence of pin prick sensation with a short-bevelled 27 G dental needle. VAS and VRS pain scores corresponding to the previous contraction, and bilateral sensory block (to pinprick), were measured every 5 min for 45 min. If a bilateral sensory block had not been achieved bilaterally at the T10 level after 30 min, and the patient was still in pain, an additional 5 ml dose of 0.2% ropivacaine was administered. If, at 45 min a bilateral block to T10 had not been produced despite this additional bolus, the patient was withdrawn from the study and the epidural was re-sited. The time at which the T10 level was achieved (and the patient was pain free) was defined as 'zero'. Patients were then randomized (computer generated numbers inserted into opaque envelopes) to receive either an intermittent administration (0.2% ropivacaine 10 ml with fentanyl 25 mcg.

Motor block was assessed bilaterally using both a modified Bromage score (0=lifts leg; 1=knee flexion; 2=ankle flexion; 3=no movement) and a straight-leg raising (SLR) score (0=no contraction; 1=visible contraction; 2=movement, gravity eliminated; 3=movement against gravity; 4=movement against gravity and resistance; 5=normal power). Unilateral motor block was defined as a difference between the two sides of at least two levels on the Bromage or SLR. Sensory and motor block assessments, and maternal heart rate and blood pressure were obtained at the same time as pain scores. Fetal heart rate was monitored continuously by cardiotocograph. Hypotension (>30 % decrease in systolic blood pressure) was treated with i.v. boluses of ephedrine 6 mg.

Demographic data collected were including age, height, weight , BMI and pre-procedural vital signs including Pulse rate, NIBP, Respiratory rate, SPO2,fetal heart rate is monitored, Pain assessment done by VAS & VRS, the level of sensory blockage and degree of motor blockage along with the supplement drugs for analgesia if needed is assessed and recorded.

3. Results

Both groups were comparable with respect to Age, Gravida, Height, Weight and BMI. The group were compared to the mean onset time, maximum height of sensory and motor blockade, total drug required and mode of delivery, patient satisfaction is comparable.

Variable	Group R1 (n=40) (%)	Group R2 (n=40) (%)	P value
Age (years)	24.13±3.46	24.15±2.76	NS
Weight (kg)	54.90±5.82	55.50±5.67	NS
Height (ft. in)	5.08±0.45	5.05±0.53	NS
Parity			
Multiparous	18 (45)	19 (47.5)	NS
Primi	22 (55)	21 (52.5)	NS
Obstetric data			
Dilation of cervix (cm)	3.43±0.64	3.33±0.73	NS
Station of vertex	2.05±1.06	2.20±0.82	NS
Effacement of cervix (%)	85±14	86±13	NS
Presence of membrane			
Absent	2 (5)	7 (17.50)	NS
Present	38 (95)	33 (82.50)	NS
P>0.05 (NS: Not significant)			

Hemodynamic data	Group R1 (mean±SD)	Group R2 (mean±SD)	P value
Baseline MAP (mmHg)	85.48±8.74	86.60±7.72	P>0.05 (NS)
Lowest MAP (mmHg)	72.00±8.34	74.33±7.70	P>0.05 (NS)
% fall of MAP from baseline	15.06	14.16	P>0.05 (NS)
Baseline heart rate (bpm)	73.53±6.66	72.53±8.05	P>0.05 (NS)
Lowest heart rate (bpm)	69±7.60	67±7.42	P>0.05 (NS)
% fall of heart rate from baseline	6.16	7.62	P>0.05 (NS)

P>0.05 (NS: Not significant), MAP: Mean arterial pressure, SD: Standard deviation

Before initiation of analgesia the mean VAS score was 9.8 in group R1 and 9.9 in group R2. Both the groups produce effective analgesia (defined as VAS <3) after single initial bolus dose without failure rate.

VAS score (mean±SD)			
Before bolus dose	9.80±0.61	9.90±0.50	*P*>0.05 (NS)
5 min after bolus dose	5.00±2.89	1.63±2.89	*P*<0.001 (HS
15 min after bolus dose	0.55±1.97	0.00±0.00	
30 min after bolus dose	0.30±1.32	0.00±0.00	
Patient distribution according to time of onset[$]			
0-5 min (%)	8 (20)	30 (75)	<0.001 (HS)
>5-15 min (%)	30 (75)	10 (25)	<0.001 (HS)
>15-30 min (%)	2 (5)	0	<0.001 (HS)
Patient distribution according to doses required			
Bolus dose only (%)	13 (32.5)	38 (95)	<0.001 (HS)
Bolus dose+1 top-up (%)	22 (55)	2 (5)	<0.001 (HS)
Bolus dose+2 top-up (%)	5 (12.5)	0	<0.001 (HS)
Duration of analgesia of bolus dose (min)	72.25±40.26 (*n*=40)	132.05±56.81 (*n*=40)	<0.001 (HS)
Mean time to first top-up (min)	58.15±22.65 (*n*=27)*	131.30±57.11 (*n*=2)*	<0.001 (HS)
Mean time to second top-up (min)	76.77±48.50 (*n*=5)**		NA
Mean number of top-up doses for each patient	0.80±0.65	0.05±0.22	<0.001 (HS)
Total dose of ropivacaine (mg)	33.75±12.16	31.50±6.62	>0.05 (NS)
Total dose of fentanyl (µg)	54.00±19.45	31.50±6.62	<0.001 (HS)

After epidural injection majority of parturients achieved VAS<3,after 5 mins of epidural bolus injection VAS score was significantly less in R2 group. All the parturients in both the groups attained a sensory blockade level of T 10 and none of the patients in both the groups showed a sensory block higher than T 10. Duration of analgesia of initial bolus dose, defined as the time until parturient requests for additional analgesia (first top-up), was calculated for all 40 patients in each group and was found to be significantly more in group R2 than in group R1. In group R2 only 2 patients required a single top-up dose and 38 patients had adequate analgesia until the delivery after initial bolus dose, whereas in group R1 only 13 parturients could achieve effective analgesia until the delivery after initial bolus dose, 22 required a single top-up dose and 5 required two top-ups ($P < 0.001$).

4. Discussion

The last few years have been marked by the arrival of new local anesthetics; ropivacaine and levobupivacaine, with reduced systemic toxicity and a better preservation of motor function.Ropivacaine 0.2% offers adequate analgesia more often than either 0.15% or 0.1% and the resultant motor blocks and hemodynamic effects are minimal[7]. Addition of fentanyl to 0.2% ropivacaine improved analgesia to a quality similar to 0.2% ropivacaine with clonidine.

In the present study, epidural labor analgesia with ropivacaine 0.2% combined with fentanyl and clonidine produced adequate labor analgesia parturients in both groups showing a 100% success rate.

However, we observed that the onset of analgesia was significantly faster when labor analgesia was initiated with 0.2% ropivacaine as reported earlier that a decrease in time for onset occurs with increasing concentrations of epidural bupivacaine[8]. Duration of analgesia of initial bolus dose was significantly more with 0.2% ropivacaine with fentanyl in our study as observed by others. Requirement of top-up doses was also significantly less frequent in 0.2% group with fentanyl group, but total dose of ropivacaine was comparable in two groups[9]. The main undesirable side-effects with ropivacaine analgesia are hypotension, bradycardia, nausea, paresthesia, and urinary retention, which are considered mild and transient. However, the side-effects observed with opioids are multivariate (nausea, pruritus, respiratory depression, lower Apgar scores in the neonate).

In the present study, no motor block was observed in both groups, which is in concordance to others. Injection delivery interval was comparable in both groups, but it was shorter as compared to others[10]. In our study, maternal expulsive effort, instrumental delivery, and neonatal status were comparable in both groups as observed by others.

No parturient had hypotension, hypersensitivity reaction, pruritus, nausea, urinary retention, vomiting, respiratory depression, weakness in the limbs or shivering, though cases of pruritus, hypotension, have been reported with epidural labor analgesia. Both groups produced good maternal expulsive efforts,

5. Conclusion

Both the concentrations are effective in producing labor analgesia. Group R2 (0.2% ropivacaine with 25 mcg Fentanyl) parturients; however, had a faster onset and significantly longer duration of analgesia with a single dose and required lesser top-ups, resulting in a significantly reduced consumption of opioids. Hence, our study favors, the use of 10 ml of 0.2% ropivacaine with 25 mcg fentanyl over 0.2% ropivacaine with 37.5 mcg clonidine for labor analgesia.

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